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Prehabilitation and rehabilitation nursing:
Balance and fall risk in community-dwelling older adults.

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Os melhores RUMOS para os Cidadãos da Região

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Abstract

Falls in community-dwelling older adults and their impact are major concerns for nurses. Balance, strength and gait impairments are known to be the strongest modifiable risk factors for falls, therefore, a focus for targeted nursing interventions.

The purposes of this research were: (1) to assess the feasibility and safety of the ProBalance program; and (2) to assess the effect of the ProBalance program, on balance, strength and gait of community-dwelling older adults with balance impairments, when compared to a control group, after a 12 weeks intervention and 12 weeks follow up.

The main randomized controlled trial (RCT) included a sample 177 older adults, 52 eligible participants were randomized to two similar groups (IG/CG). Assessments were at 0 (pre-test), 12 (post-test), and 24 weeks (follow up). Analysis included completers (n=46). The ProBalance program included gait, balance, functional training, strengthening and endurance, flexibility, and 3D training. The intervention was administered on a group basis by one trained rehabilitation nurse, in 90 min sessions, 2 days per week, for 12 weeks. Balance was assessed by the Fullerton Advanced Balance (FAB) scale. Strength was assessed as in the Senior Fitness Test battery and gait parameters by the 30-Foot Walk Test. A pilot study focused on the feasibility of this research (RCT, n=12). The protocols for assessments and intervention were fully applied, and no adverse events were associated to participation. Eligibility rate was low (15%) and the attrition rate was null. Reliability of all measures, assessed by intra-class correlation coefficient (R), ranged between 0.689 and 1.000.

This study demonstrated beneficial effects of the ProBalance program in improving balance and reducing fall risk in the IG, immediately after the intervention. While the IG reduced fall risk by 40%, the CG experienced a fall risk increase by 11.6%. Significant effects were seen in strength; and gait velocity and cadence at maximal speed at post-test. Short-lasting effects were verified at follow-up, with significant decreases occurring in balance scores and strength tests for the IG.

Overall, this research demonstrated the feasibility, safety and efficacy of the ProBalance intervention in community-dwelling older adults with balance impairments. Future research should focus on the long term-efficacy of the ProBalance intervention and include pragmatic trials to assess the effectiveness and cost-effectiveness of this intervention in "real world" clinical settings.

Key words: Gerontological rehabilitation nursing, Community-dwelling older adults; Fall risk; Balance; ProBalance Program.

Resumo

As quedas em adultos idosos residentes na comunidade e o seu impacto são problemas relevantes para os enfermeiros. Os défices no equilíbrio, na força e na marcha são os mais fortes fatores de risco modificáveis para a queda, constituindo-se como um foco para intervenções de enfermagem.

Os objetivos desta pesquisa foram: (1) avaliar a exequibilidade e segurança do programa ProBalance; e (2) avaliar o efeito desta intervenção de enfermagem de reabilitação no equilíbrio, força e marcha, num grupo de adultos idosos residentes na comunidade com défices de equilíbrio, após 12 semanas de intervenção e 12 semanas de *follow up*, quando comparados com um grupo de controlo.

O ensaio clínico controlado e randomizado (RCT) principal incluiu uma amostra 177 idosos, dos quais 52 foram randomizados e alocados a dois grupos similares (IG/CG). Os participantes foram avaliados na semana 0 (pré-teste), 12 (pós-teste) e 24 (*follow up*). A análise foi por protocolo (n = 46). O programa de reabilitação incluiu treino de marcha, equilíbrio, funcionalidade, força muscular e resistência, flexibilidade e treino 3D. A intervenção foi administrada em grupo por uma enfermeira especialista em reabilitação, em sessões de 90 minutos, 2 dias por semana, durante 12 semanas. O *outcome* principal foi o equilíbrio, avaliado através da *Fullerton Advanced Balance Scale* (FAB). A força foi avaliada através da bateria *Senior Fitness Test* e a marcha através do teste de caminhada de 30 metros. Um estudo piloto foi desenvolvido para testar a exequibilidade da pesquisa (RCT, n = 12). Os protocolos de avaliações e intervenção foram aplicados integralmente, sem eventos adversos associados à intervenção. A taxa de elegibilidade foi baixa (15%) e a taxa de atrito foi nula. A fiabilidade das medidas foi avaliada com recurso ao coeficiente de correlação intra-classe (R), que variou entre 0,689 e 1,000.

Este estudo verificou o efeito do programa ProBalance na melhoria do equilíbrio, imediatamente após a intervenção. Neste momento, enquanto o IG reduziu o risco de queda em 40%, o CG experimentou um aumento de risco de cair de 11,6%. Efeitos significativos foram também observados na força; e na velocidade da marcha e cadência à velocidade máxima, no pós-teste, para o IG. No follow-up, decréscimos significativos verificaram-se no equilíbrio e testes de força para o IG.

Esta pesquisa demonstrou a exequibilidade, a segurança e a eficácia do programa ProBalance em idosos residentes na comunidade, com défices de equilíbrio. Pesquisa futura deve focar a eficácia da intervenção a longo prazo e incluir ensaios pragmáticos para avaliar a efetividade e custo-efetividade desta intervenção no contexto clínico.

Palavras chave: Enfermagem de reabilitação gerontológica, Adultos idosos residentes na comunidade; Risco de queda; Equilíbrio; Programa ProBalance.

Chapter 1
Introduction

1.1 Introduction to the study topic
1.2 Developing complex interventions in nursing sciences
1.3 The model behind the nursing approach
1.4 Operational definition of central concepts
1.5 Aims and hypothesis
1.4 Outline of the thesis
1.5 References

1.1 Introduction to the study topic

As worldwide, the population in the European Region is ageing rapidly. By 2010, an estimated 15% of the overall population was aged 65 years and over, with this age group becoming the fastest growing segment of the population. Yet, this age group is projected to represent more than 25% of the population in the European Region by 2050 (WHO, 2013). Portugal is one of the most aged countries in Europe, with the older adult segment of the population (65 and older) increasing from 16% in 2001 to 19% in 2011 (Statistics Portugal, 2012a). Although the Autonomous Region of Madeira (ARM) continues to be one of the less aged regions in the country, the older adult segment has also increased, comprising 14,9% of the population in 2011, while in 2001 it represented 13,7% (Statistics Portugal, 2012b).

Following the ageing of the population, further demands need to be met by the health care, including the availability of an adequately trained health workforce and adequate services (WHO, 2013). Among other geriatric problems, falls in community-dwelling older adults is a major concern for the health care and for the society, due to its impact on individual and public health (WHO, 2007). Particularly, fall-related injuries represent one of the main causes of longstanding pain, functional impairment, disability, and death in this population (Kannus, Sievänen, Palvanen, Järvinen, & Parkkari, 2005).

Previous studies have shown that falls are the most frequent accident and the leading cause of fatal injury in older adults. In the European Union, 53% of the total injury deaths and 82% of fatal fall injuries, happened in people 60 years and older. In this age group, falls accounted for 28% of all causes of injury-related deaths (EuroSafe, 2013). In Portugal, 15% of domestic and leisure accidents happened in the older adults (65 and older) and falls accounted for 87.1% of all accidents in older adults aged 65-74 years (NHORJ, 2011). In the ARM, Portugal, Gouveia (2011) reported that 36% of a sample of community dwelling older adults had, at least, one fall in the past year. This is in line with worldwide studies showing that at least, 30% of community-dwelling older adults (aged 65 and older) experienced one or more falls each year and that 10 to 15% of these falls were associated with serious injuries (American Geriatrics Society, British Geriatrics Society, & American Academy of Orthopaedic Surgeons Panel on Falls Prevention, 2001; Gillespie et al., 2012; Rubenstein, 2006; Sturnieks, George, & Lord, 2008). The problem is estimated to worsen, since the rates of such injuries seem to be rising in many areas, accompanying the number of older people in both the developed and developing world (Kannus, et al., 2005).

In regard to their origin, falls seem to be multifactorial. Chronic conditions, balance and gait impairments, functional disabilities, general physical inactivity, vision problems, cardiovascular factors, and medications are predisposing factors for falls, while home hazards, footwear, and multifocal or new glasses are precipitating factors (Tinetti & Kumar, 2010). Nevertheless, research has shown that balance, strength and gait impairments are the strongest modifiable risk factors for falls (Rubenstein & Josephson, 2002; Tinetti & Kumar, 2010; Deandrea et al., 2010).

Due to the association between balance impairments, reduced physical functioning, and increased risk of falling in older adults, research has been conducted to analyze the effects of exercise interventions on balance (Howe, Rochester, Neil, Skelton, & Ballinger, 2011). Specifically, the effect of community-based group-structured exercise programs has been extensively studied over the past 20 to 25 years (Rose, 2008), allowing the scientific community to draw some conclusions on this topic. Nowadays, there is scientific evidence that some types of exercise, including gait, balance, co-ordination and functional tasks, strengthening exercise, 3D exercise and multiple exercise types, are moderately effective in improving clinical balance outcomes and reducing falls in older adults (Balzer, Bremer, Schramm, Lühmann, & Raspe, 2009; Costello, & Edelstein, 2008; Gillespie et al., 2012; Sherrington et al., 2008; Howe, et al., 2011).

Yet, the majority of previous research has targeted healthy older adults or frail older adults, in detriment of balance-screened older adults (Howe et al. 2011). In this population, theory-driven rehabilitation programs targeting important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness, have proven to be effective in reducing fall risk among older adults identified as moderate-to-high risk for falls (Rose, 2011). Therefore, improvements in balance of community-dwelling older adults with balance impairments are expected in further research on the effect of this type of multidimensional approach to balance. The ProBalance program was developed in response to this expectation, inspired by the FallProof Program (Rose, 2010). It is a theory-driven nursing intervention, adopting a multidimensional approach to balance and mobility in independent-living older adults with balance impairments, targeting important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness (Rose, 2011).

In the context rehabilitation nursing practice, early identification of age-related changes and risk factors for falls affecting the older adults, such as balance impairments, and the delivery of targeted training are important to prevent older adults from progressing to more severe impairments or experiencing a serious fall. Nevertheless, research is necessary to provide robust evidence on the effect of this type of interventions, and particularly nursing interventions.

The gap in the available knowledge on this topic led us to question: “How can rehabilitation nurses improve balance and reduce fall risk in community-dwelling older adults with balance impairments?” and “Is a multidimensional rehabilitation nursing program effective in improving balance and reducing fall risk in older adults with balance impairments?”

On this basis, with the present investigation, designated *Prehabilitation and Rehabilitation Nursing: Balance/ fall risk in the community-dwelling older adults - Randomized Controlled Trial,* we intend to contribute to the overall knowledge on the effect of a rehabilitation nursing intervention targeting community-dwelling older adults screened for balance impairments.

1.2 Developing complex interventions in nursing sciences

We might consider that many nursing interventions are complex, according to the Medical Research Council (MRC, 2008) definition. This council describes complex interventions as interventions that contain several interacting components. This complexity may be due to the range of possible outcomes, or their variability in the target population, and the quantity of elements in the intervention itself.

In face of the identification of these characteristics, in the context of a rehabilitation nursing approach to older adults with balance impairment, the ProBalance project was developed following the MRC (2008) guidance for developing, evaluating and implementing complex interventions. This guidance describes the process from development to implementation of a complex intervention as composed by specific stages with key functions and activities, organized in a wide range of different forms, due to interactions between the phases and the fact that their sequence is nor linear or cyclical.

Figure 1.1 illustrates this dynamic process and the key activities included in each phase of the MRC guidance for developing, evaluating and implementing complex interventions.

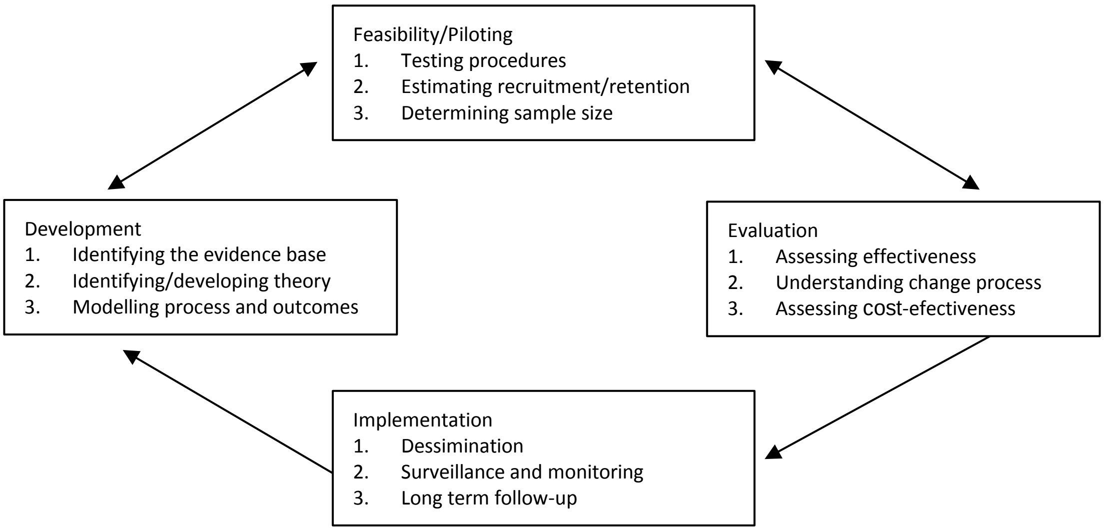

Figure 1.1 Schematic of the main stages and key activities of the process of developing and evaluating complex interventions. Adapted from: “Developing and evaluating complex interventions: new guidance”, by the Medical Research Council, p.8. Copyright 2008 by the Medical Research Council.

Halberg (2006) has argued that nurse researchers need to take the next step and contribute to a new generation of nursing research with great impact on clinical practice, providing knowledge that the consumers, the patients and the providers are concerned.

Therefore, possible nursing interventions, developed on the basis of previous exploratory studies, need testing. Only research can ensure that they are applicable to practice, are not harmful and will cause the expected outcome. In addition, research can provide us with an understanding of the mechanisms underlying people’s reactions to health problems, as well as the results of certain interventions (Halberg, 2009).

Halberg (2009) suggests that focusing nursing research on the outcome of different interventions, psychosocial, behavioral or physical, requires critical reflection on the designs used to study effects. Although feasibility of randomized controlled trials (RCT) is, in many cases compromised in clinical nursing settings, this is the gold standard study design to address this type of problem. The same author, states still that even though it is difficult to develop research on interventions in clinical nursing care and frequently the conclusions fail to explain causality, this type of research is needed to advance clinical nursing knowledge.

Given all these challenges, we believe that the present research stands as relevant in the context of nursing sciences and the provided knowledge will be of major importance for nurses who care for community-dwelling older adults and for the older adults themselves.

1.3 The nursing theory supporting the approach to older adults

A nursing theory provides the theoretical background to this research – the “Functional consequences theory for promoting wellness in older adults” (Miller, 2012). This theory was specifically designed to provide a framework for nursing care in older adults, recognizing that, in older adults, age-related changes and risk factors combine to cause negative functional consequences, and nursing interventions are planned to counteract or minimize these negative functional consequences, thereby promoting positive functional consequences or an optimal level of function (wellness outcome).

Considering the aims of the “Functional consequences theory” and its coherence with rehabilitation nursing demands, we believe that this theory is a suitable framework for the development of this approach to older adults with balance impairments.

In addition to the theoretical framework, an independent concept was found relevant for this research, namely, the concept of prehabilitation. This concept has been introduced in the rehabilitation domain to describe a preventive intervention meant to enhance functionality, prior to the occurrence of an expected stressor (Spain, 1985) and it has also been suggested as an important concept in the care of older adults. In this specific area of care, it refers to interventions aimed at promoting functionality while delaying or minimizing disability (Gill et al., 2003; Gill et al., 2004; Carli & Zavorsky, 2005; Halberg, Cornélissen & Beaty, 2008), which is also supportive of our approach to older adults in regard to falls as negative event.

1.4 Aims and hypothesis

From a rehabilitation nursing perspective, specifically in view of the “Functional consequences theory for promoting wellness in older adults” (Miller, 2012), and considering the potential effects of prehabilitation exercise interventions on balance control, designing and testing a targeted balance intervention is the main topic of this research.

The purpose of this research project are: (1) to assess the feasibility and safety of the ProBalance program (a rehabilitation nursing intervention) in community-dwelling older adults from Madeira, Portugal; and (2) to assess the effect of the ProBalance program in a group of community-dwelling older adults from Madeira, Portugal, on balance, muscular strength and gait parameters, when compared to a control group after a 12 weeks duration intervention and 12 weeks follow up.

In addition to these objectives, three research hypotheses were formulated to guide interpretation and conclusions to be drawn from the future results of this research:

(1) The group of community-dwelling older adults involved in the ProBalance program will have significantly higher levels of balance and lower risk for falling when

compared with the group that did not receive the ProBalance intervention, after a 12 week duration intervention and 12 week follow up (H1);

(2) The group of community-dwelling older adults involved in the ProBalance program will have higher levels of muscular strength (lower body and upper body) when compared with the group that did not receive the ProBalance intervention, after a 12 week duration intervention and 12 week follow up (H2);

(3) The group of community-dwelling older adults involved in the ProBalance program will have better results in gait parameters when compared with the group who did not receive the ProBalance intervention, after a 12 week duration intervention and 12 week follow up (H3).

1.5 Operational definition of central concepts

To ensure consensus when analyzing and interpreting the information on this research report, we present the operational definition of the central concepts in this investigation.

Gerontological rehabilitation nursing

Gerontological rehabilitation nursing is a field of nursing practice that focuses on the specific necessities of rehabilitation clients in old age, specifically, targeting age-related changes and functional limitations associated with injuries or illness. The goal of gerontological rehabilitation nursing is to assist older adults to achieve an optimal well-being, prevent complications, and enhance their quality of life (Easton, 1999; Mauk, 2006).

Community-dwelling older adults

In the context of this research, the community-dwelling older adult is an adult aged 65 and over (Jones & Rose, 2005), who lives in the community and is able to walk without any assistance.

Fall risk

Fall risk is an increased vulnerability to falls, derived from the presence of biological, behavioral, socioeconomic and environmental factors that increase the likeliho
od of falling (Miller, 2011; WHO, 2007). These risk factors are often described as predisposing or precipitating factors for falls. Balance, strength and gait impairments are considered predisposing factors, while home hazards and type of glasses worn are viewed as precipitating factors (Tinetti & Kumar, 2010). However, the majority of falls result from the interaction between predisposing and precipitating factors (Rubenstein, 2006).

Balance

Balance relates to the ability to maintain equilibrium, even when you are exposed to an unstable condition, so that the position of the center of mass can move vertically or horizontally within the base of support, without the person falling (Chapman, 2008). It is a complex skill that involves the detection and integration of sensory information and the execution of appropriate motor responses to control body position that are specific to the environmental and task demands (Rose, 2010; Winter, Patla, & Frank, 1990).

ProBalance program

The ProBalance program is an exercise intervention designed to improve balance of community-dwelling older adults with balance impairments. It is inspired by the FallProof Balance and Mobility Program (Rose, 2010), and as in this program, it is a theory-driven intervention, adopting a multidimensional approach to balance and mobility, targeting important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness (Rose, 2011).

1.6 Outline of the thesis

The present research project - *Prehabilitation and Rehabilitation Nursing: Balance/ fall risk in the community-dwelling older adults - Randomized Controlled Trial* – will be reported in this thesis, throughout eight chapters.

After this general introduction (chapter one), chapter two will describe in a concise way the theoretical and scientific background to this research. The first topic addressed in this section is the conceptual model that supports our nursing approach to older adults with balance impairments. The "Functional consequences theory for promoting wellness in older adults" and the concept of "Prehabilitation" are presented and discussed as basis for nursing planning. The next topic is falls in community-dwelling older adults, followed by discussion on balance in this population and lastly the rationale for the ProBalance intervention.

Chapter three (Method) will report the methodological options in the present research. Definitions of study type, investigation question, sample and participants, recruitment and enrolment, intervention and control, outcome and interfering variables, instruments and assessment, ethical considerations, and quality control are specified.

Chapters four, five, six and seven are original articles elaborated in the context of this research, which describe all the findings of this research. Chapter four includes a theoretical article: Therapeutic exercise in Gerontological Rehabilitation: A literature analysis. Chapter five is composed by an article focused on the pilot study. This article is entitled: The ProBalance Program for improving balance in older adults: A pilot study. Chapter six comprises the first article focused on the main RCT, namely in assessing the effect of the ProBalance intervention on our primary outcome (balance). The article is entitled: The ProBalance Program improves balance and reduces fall risk in community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial. The last article included in this thesis consists on chapter seven: The effect of the ProBalance Program in strength and gait of community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial. In this article, the effect of the intervention on the secondary outcome (strength and gait) is assessed.

The last chapter in the thesis is Chapter eight, describing the general conclusion of this research. In this section we give an overview of the study findings and address the limitations and strengths of the study design, as well as, the implications for clinical practice and future directions.

References are presented at the end of each chapter and the information included in the original research articles is in line with the CONSORT Statement guidelines for reporting clinical trials (Boutron et al., 2008).

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Chapter 2

Theoretical and scientific background: State of art

2.1 The Functional consequences theory for promoting wellness in older adults and the concept of Prehabilitation
2.2 Falls in community-dwelling older adults
2.3 Balance in older adults
2.4 The ProBalance intervention
2.5 References

Bridge

In this chapter, we approach the theoretical and scientific background to our research project, starting with a description of our nursing perspective in the care of older adults. Following an overview of the current knowledge about falls, balance in older adults will be addressed as the central topic of this research. Information of the systems that contribute to balance as well as the age-related changes that affect balance are discussed in this section. Finally, we review the most relevant literature regarding balance assessment and interventions aimed at improving the balance of older adults, discussing the rationale for the ProBalance intervention, which will be tested in the context of this research.

2.1 The Functional consequences theory for promoting wellness in older adults and the concept of Prehabilitation

Gerontological rehabilitation nursing is a specific nursing practice that focuses on the distinctive necessities of elderly rehabilitation clients, namely, age-related changes and functional limitations associated with injuries or illness. The goal of gerontological rehabilitation nursing is to assist older adults achieve an optimal physical, mental, and psychosocial well-being, prevent complications, and enhance their quality of life (Easton, 1999; Mauk, 2006). Rehabilitation itself is a complex process that demands a multidisciplinary and theoretically-based approach to care (Lutz & Davis, 2008). Nevertheless, this discussion will focus on models that guide practice in rehabilitation nursing, especially in the gerontological area.

Based on specific knowledge from other disciplines, rehabilitation nursing practice inherits a theoretical background from biological, psychological, sociological, and anthropological theories that focus on life processes, well-being, and optimal function. Derived from these basic disciplines, many nursing theories have been developed and considered relevant to rehabilitation nursing practice. Examples include Roy's adaptation model, Roger's model of the science of unitary human beings, King's general systems framework and theory of goal attainment, Neuman's systems theory, the Omaha system, Roper's model for living, Gordon's functional health patterns, Virginia Henderson's humanistic theory, Hall's philosophy of nursing, and Orem's theories related to self-care (Easton, 1999; Lutz & Davis, 2008).

In addition to our discussion of these theoretical perspectives, we wish to draw attention to a theory developed during the nineties and recently updated by a gerontological clinical nurse specialist, Carol Miller (Miller, 1990; 2012). The "Functional consequences theory for promoting wellness in older adults" is a theoretical approach that addresses the nurse's role in enhancing health, functioning, and quality of life in older adults. This wellness approach draws on multidisciplinary knowledge on aging and from the conceptualizations of many nursing theorists, namely, Florence Nightingale, Virginia Henderson, Imogene King, Jean Watson, Martha Rogers, Margaret Newman, Calista Roy, Rosemarie Parse, and Madeleine Leininger. Central to the theory is Dunn's definition of wellness. Wellness is not a simple condition (opposite to sickness), "but rather a complex state made up of overlapping levels of wellness", associated with a person, who is a physical, mental, and spiritual unit (Dunn, 1959, p.786).

Miller (2012) introduces innovative concepts such as functional consequences, age-related changes, and risk factors, and describes a comprehensive conception of the person, nursing, health, and the environment. Functional consequences are described as observable effects of actions, age-related changes, and risk factors that influence quality of life and the older adult's performance of activities of daily living. These consequences can be negative if they interfere negatively with the person's level of functioning and quality of life. On the other hand, the consequences can be positive, if they facilitate the attainment of an optimal level of performance (i.e., the highest level of functioning and lowest dependency possible). When positive functional consequences are the result of nursing interventions, they are called wellness outcomes. Age-related changes are described as irreversible, inevitable, and progressive changes occurring in older-adulthood, independently of external and pathological conditions. While on a physiological level, these changes are normally degenerative, on psychological and spiritual levels, they comprise potential for growth. Risk factors are, in contrast, conditions that enhance the older adult's vulnerability to negative functional consequences, such as diseases, unhealthy lifestyle and negative attitudes towards care. A person is defined as an older adult whose functional performance is affected by age-related changes and risk factors. When older adults are dependent on others for daily needs, their caregivers are also considered an integral focus of nursing care. As for the concept of nursing, the author states that nursing aims to minimize the negative effects of age-related changes and risk factors, and thereby promote wellness outcomes. Health is defined as the ability of older adults to achieve their highest level of functional performance (in terms of spiritual, psychosocial, physiological functions) and quality of life, despite age-related changes and risk factors. Also, it encompasses well-being and quality of life as defined by each older adult. Lastly, the concept of environment is defined as the external conditions, including caregivers. It can be considered a risk factor if it interferes negatively with function, or an intervention if it leads to improved function.

Six premises support this model: (1) holistic nursing care address the body–mind–spirit interconnectedness of each older adult and wellness incorporates more than physiological functioning; (2) although age-related changes are inevitable, most problems affecting older adults are associated with risk factors; (3) older adults experience positive or negative functional consequences as a result of the combination of age-related changes and additional risk factors; (4) nursing interventions intend to alleviate or modify the negative functional consequences of risk factors; (5) nurses can promote wellness in older adults through health promotion and other nursing interventions that address the negative functional consequences; (6) nursing interventions result in positive functional consequences, also called wellness outcomes, that enable older adults to function at their highest level despite the presence of age-related changes and risk factors (Miller, 2012).

At a practical level, the "Functional consequences theory" provides a framework for promoting wellness in older adults. Nurses assess the age-related changes, risk factors, and derived functional consequences, aiming to identify the factors that can be addressed by nursing interventions and converted in wellness outcomes. Optimally, in a multidisciplinary approach, the nursing intervention should target modifiable risk factors aiming to minimizing negative functional consequences, while promoting higher levels of function (wellness outcome). Figure 2.1 illustrates the theory, showing how age-related changes and risk factors combine to cause negative functional consequences and nursing interventions are planned to counteract or minimize these negative functional consequences, resulting in wellness outcomes.

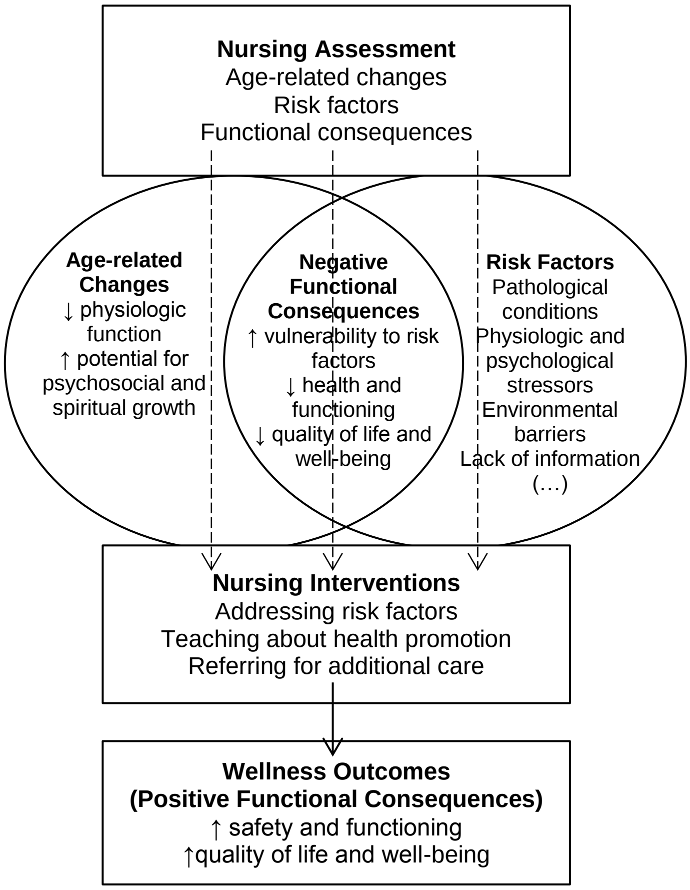

Figure 2.1 Schematic representation of the "Functional Consequences Theory for Promoting Wellness in Older Adults". Adapted from: "Nursing for wellness in older adults", by Miller, p.38. Copyright 2012 by Wolters Kluwer Health | Lippincott Williams & Wilkins.

Although limited literature is currently available about the application of this theory to specific settings, Kozak-Campbell and Hughes (1996) published a report on its use in a hospital setting. This report suggested that the "Functional consequences theory" is a useful tool for assessing and intervening in older adult care.

Considering the aims of the "Functional consequences theory" and its response to most of rehabilitation nursing demands, we believe that this theory is particularly relevant to the practice of gerontological rehabilitation nursing in the community setting that is aimed at lowering fall risk.

One independent concept that we consider relevant for this research is the concept of “Prehabilitation”. This concept has been introduced in the rehabilitation domain to describe a preventive intervention meant to enhance functionality, prior to the occurrence of an expected stressor, such as a surgery. First mentioned by Spain (1985), the reference to prehabilitation appears to have been first linked to sports medicine and injury prevention in athletes. More recently, clinical rehabilitation has borrowed the concept, applying it to preventive interventions. Although mostly used in circumstances of preoperative care (i.e., conditioning prior to the surgery), as a means to promote functionality and minimize disability (Jaggers et al., 2007; Kim, Mayo, Carl, Montgomery & Zavorsky, 2009; Nielsen, Andreasen, Asmussen & Tønnesen, 2008; Nielsen, Jørgensen, Dahl, Pedersen & Tønnesen, 2010), prehabilitation has also been suggested as an important concept to apply to the care of older adults. In this field, it refers to interventions aimed at promoting functionality while delaying or minimizing disability (Gill et al., 2003; Gill et al., 2004; Carli & Zavorsky, 2005; Halberg, Cornélissen & Beaty, 2008).

Both the “Functional consequences theory” and the concept of “Prehabilitation” provide rationale to our nursing approach to fall risk in older adults. On this basis, we consider that a great emphasis should be given to the identification of age-related changes and risk factors affecting the older adults, as a guide for a targeted intervention in rehabilitation nursing practice aiming to promote functional gains (wellness outcomes).

2.2 Falls in community-dwelling older adults

The present subchapter will discuss the epidemiology of falls and identify the major risk factors currently described in the literature. Before addressing these issues, however, we will begin by defining a fall.

Fall Definition

In a pioneering paper on falls published in the 1980s, Tinetti, Speechley, and Ginter (1988) defined a fall as “an event which results in a person coming to rest unintentionally on the ground or other lower level, not as a result of a major intrinsic event (such as stroke) or overwhelming hazard” (p.1702). However, there has been a wide variety of definitions used in subsequent studies, making it difficult to compare the outcomes of intervention studies.

In face of this lack of standardization, the collaborative project - Prevention of Falls Network Europe (ProFaNE) developed a common set of outcome definitions and measures for future trials or meta-analysis in fall injury prevention. The resulting recommendations generated by an international expert consensus include a fall definition. Fall is defined as “an unexpected event in which the participant comes to rest on the ground, floor, or lower level” (Lamb, et al., 2005; p.1619). For the purpose of this research, the ProFaNE definition of a fall was adopted.

Epidemiology of falls

Adults aged 65 years and older have higher death rates from injuries than any other age groups. This age group is more likely to be injured as a result of various factors, such as medical problems, impaired vision, and/or gait and balance impairments. In addition, their injuries are more likely to be severe in case of osteoporosis and frailty (Sethi, Racioppi, Baumgarten, & Vida, 2006). Falls are a frequent cause of injury in older adults and they can be a precipitating cause of a decline in function and independence (Sturnieks, St George, & Lord, 2008). A reasonable explanation could be the older adults’ diminished capacity to recover and the fact that, when injured, older adults are more vulnerable to fatal complications and longer periods of illness (Sethi, Racioppi, Baumgarten, & Vida, 2006). As a result, fall-related injuries in older adults are the leading cause of injury-related hospitalization and are associated with longer hospital stays and greater mortality than in other age groups. For example, in the European Union (EU), 53% of the total injury deaths and 82% of fatal fall injuries, happen in people 60 years and older. In this age group, falls account for 28% of all causes of injury-related deaths, and are therefore the leading cause of fatal injuries in this region (EuroSafe, 2013). Moreover, it is estimated that 6.7 million older adults are treated for an injury in each year, and one third of those lead to hospital admission in EU hospitals. Fall-related injuries account for a higher than average hospitalization rate and for an important part of the total direct medical cost due to injuries in this age group (EuroSafe, 2013).

In the last 30 years, several studies worldwide have described data about falls (Tinetti, Speechley, & Ginter, 1988; Blake et al.; 1988; Campbell et al., 1990; Delbaere et al., 2010; Kelsey, Procter-Gray, Hannan & Li, 2012). Although comparability across the various studies is not possible, due to the use of different designs, methods and definition of fall, there is general agreement that falls are one of the most common and serious problems facing the older adult population. Estimates that at least 30% of community-dwelling older adults (aged 65 and older) experience one or more falls each year and 10 to 15% of these falls are associated with serious injury are frequently mentioned (American Geriatrics Society, British Geriatrics Society, & American Academy of Orthopaedic Surgeons Panel on Falls Prevention, 2001; Gillespie et al., 2012; Rubenstein, & Josephson, 2002; Rubenstein, 2006; Sturnieks, St George, & Lord, 2008; WHO, 2007).

In Portugal, it is known that, in 2008, 15% of all domestic and leisure accidents registered in the emergency units were recorded in the older adult population (65 years and older) with falls accounting for 87.1% of all accidents in people aged 65-74, and 92.3% in those adults aged 75 years and over (NHORJ, 2010). Despite these statistics, the prevalence of falls is frequently under reported. It is important to note that most epidemiological data, like that reported by NHORJ (2010), provides limited information about the real incidence of falls, mostly because data collection is associated with admissions to an emergency hospital and excludes all falls that didn't require medical care.

In the Autonomous Region of Madeira (ARM) – Portugal, an epidemiological and comprehensive study focused on aging and health determinants, also described the magnitude of this problem in a representative sample of community-dwelling older adults from Madeira Islands (Gouveia, 2011). In this study, of the 619 older adults who completed a health questionnaire, 36% reported at least one fall in the past year.

Risk factors for falls

Falls are multifactorial in their origin (Rubenstein & Josephson, 2006). Because a single specific cause for falling frequently cannot be identified, several factors are mentioned in the literature, and often described as predisposing or precipitating factors for falls. For example, chronic medical conditions, balance and gait impairments, functional disabilities, vision problems, cardiovascular factors, and medications are considered to be predisposing factors while home hazards, footwear, and type of glasses worn, are viewed as precipitating factors (Tinetti & Kumar, 2010). Most falls, therefore, result from the interaction between predisposing and precipitating factors (Rubenstein, 2006).

For further understanding of this topic, we will identify the major fall risk factors described in the current literature by categories. The World Health Organization (WHO) (2007) categorizes the major risk factors for falls into four main dimensions: (1) biological; (2) behavioral; (3) socioeconomic; and (4) environmental risk factors. Table 2.1 summarizes this information.

Table 2.1 Biological, behavioral, socioeconomic, and environmental risk factors for falls (WHO, 2007).

Risk Factor Category	Examples
Biological	Demographic characteristics; Chronic illnesses; Decline in physical, cognitive, and affective abilities.
Behavioral	Polimedication; Inappropriate footwear; Lack of exercise; Excessive alcohol intake.
Socioeconomic	Low income and educational level; Inadequate housing; Lack of social interactions; Limited access to health and social services; Lack of community resources.
Environmental	Poor building design; Slippery floors and stairs; Loose rugs; Cracked or uneven sidewalks.

Biological risk factors

Biological risk factors for falls include non-modifiable demographic characteristics, such as age, gender, and race. Specifically, being older than 80 years and female are frequently associated with a higher risk for falls (Ambrose, Paul, & Hausdorff, 2013; Kempen et al., 2009; Rose, 2010). In young-old adults, the rate of falls is similar for both men and women. Yet, oldest women fall more often than men the same age. In regard to race, evidence from the United Kingdom and the United States suggests that Caucasian older adults fall more frequently than African tribes of the Caribbean, Hispanics, or South Asians; no studies were found reporting national differences in continental Europe (Dionyssiotis, 2012).

Chronic medical conditions are also considered important biological factors for falls, particularly those that affect mobility, balance, cognition, and vision. An increased risk of falling has been identified in older adults who suffer from Parkinson’s disease, stroke, osteoporosis, arthritis, or dementia. A moderate-to-strong association between these diseases and the risk for falls has been reported (Rose, 2010). Depression, abnormal neurological signs or impaired cognition, incontinence, foot problems, dizziness, orthostatic hypotension, vestibular disorders, acute illness, and the coexistence of different chronic conditions are also reported as medical factors associated with falls (Lord, Sherrington, Menz, & Close, 2007). Besides known, the identification of many biological risk factors can be complex, mostly because the underlying cause of the fall or mechanism behind the symptoms can be misleading.

An example is dizziness, a symptom that can be associated with true vertigo (i.e., a sensation of rotational movement, that may indicate a disorder of the vestibular apparatus such as benign positional vertigo, acute labyrinthitis, and Meniere's disease), a gait disorder (when symptoms are described as imbalance when walking), or to cardiovascular problems, hyperventilation, orthostatic hypotension, drug side-effects, anxiety, or depression (when the older adult reports a sensation of vague lightheadedness) (Rubenstein & Josephson, 2002).

The biological category of risk factors also includes age-related changes in physical, cognitive, and affective abilities (Rose, 2010; WHO, 2007). Rubenstein (2006) reports that older adults have stiffer and less coordinated gait patterns than younger people. With ageing, there is a decline in postural control, body-orienting reflexes, muscle strength and tone, which adversely affect the older adult's ability to avoid a fall after a trip or slip. Also, a decline in sustained attention contributes to increased fall risk. The responsible mechanism is age-related and results from noradrenaline depletion and primary changes in the frontal cortex. Thus, recent research suggests that sustained attention variability may provide a new and important biomarker for fall risk in older adults (O'Halloran et al., 2011).

Confusion and cognitive impairment may also reflect underlying systemic or metabolic processes (e.g., electrolyte imbalance, fever) that cause both the cognition impairment and the fall itself (Rubenstein & Josephson, 2002).

Age-related impairments in vision, hearing, and memory tend also to increase the occurrence of trips and stumbles. For example, decreased visual acuity, depth perception, and contrast sensitivity, as well as the presence of cataracts are associated with a higher risk for falls (Tinetti, 2003).

In addition to some of the age-related changes mentioned previously, Rubenstein and Josephson (2002) also suggest that some of the age-related changes (e.g., gait problems and muscular weakness) can stem from specific dysfunctions of the nervous, muscular, skeletal, circulatory, and respiratory systems (such as those associated with stroke, parkinsonism, and arthritis) and also from simple deconditioning associated with low levels of activity, rather than from the aging process per se. This idea reflects the importance of considering the interaction between risk factors, specifically, in this case, biological and behavioral factors.

Behavioral risk factors

Behavioral risk factors for falls include multiple medication use, low levels of physical activity, inappropriate diet, excessive alcohol intake, inadequate footwear, and other risk-associated behaviors (WHO, 2007). Medication use is often discussed in the literature, since it is one of the most easily modifiable risk factors for falls. Not only are the pharmacological properties and side effects of certain drugs important to understand, but also the age-related changes in pharmacokinetics that can impact postural stability, and therefore increase the risk for falls (Lord, Sherrington, Menz, & Close, 2007; Rubenstein & Josephson, 2002). Fall-risk increasing medications include drugs prescribed for cardiovascular diseases such as digoxin, anti-arrhythmics, and diuretics, benzodiazepines, antidepressants, antiepileptics, antipsychotics, antiparkinsonian drugs, opioids and urological spasmolytics. However, psychotropic and benzodiazepine use are the most consistently associated with falls (Hill & Wee, 2012; Huang et al., 2012), even when taking into account underyling disease (Lord, Sherrington, Menz, & Close, 2007). Independently of the type of medication, polymedication (described as the use of four or more medications) is also associated with increased fall risk (Lord, Sherrington, Menz & Close, 2007; Rose, 2010; Tinetti & Kumar, 2010; Tinetti, Speechley, & Ginter, 2008). Also, the use of inappropriate footwear is a behavioral factor associated with the occurrence of slips and trips. Examples of poor footwear include shoes with high heels or slippery soles (Lord, Sherrington, Menz, and Close; 2007).

Physical inactivity is also a behavioral factor that affects mobility and balance in older adults, therefore, increasing fall risk. Regular physical activity, combined with an appropriate diet, is also important for global health and wellbeing (Rose, 2010). Alcohol intake has been identified as a risk factor for falls by Tinetti & Kumar (2010), based on expert opinion and clinical experience. Alcohol may have an adverse impact on perception and cognition, and an association with risk-taking behaviors. Another behavioral risk factor is fear of falling. Inappropriate fear of falling includes being fearless or being fearful. These two situations seem to be relevant when discussing falls in older adults. Delbaere et al. (2006) have studied the relationship between these situations and falls. Their results showed that older adults with an inappropriate low fear of falling were physically strong, but had poor balance. The lack of awareness of their risk for falls enhanced their exposure to dangerous situations. On the other hand, those with an inappropriate high fear of falling had low muscle strength and restricted activities. However, fear of falling can arise prior to a fall and/or as a result of a fall. Lee, Mackenzie, and James (2008) state, however, that the experience of falls directly influences the fear. These authors found that most participants in their study did not fear falling until they had experienced a fall themselves (faller status). Rubenstein and Josephson (2002) also recognize fear of falling as a negative consequence of falls, and also suggest that loss of confidence in the ability to move safely can cause further functional decline, depression, feelings of helplessness, and social isolation.

Socioeconomic risk factors

Although socioeconomic factors are not directly related to the risk of falls, low income and educational levels, the lack of social interactions and limited access to health and social care or services can affect the older adults' health condition and therefore increase their risk for falls (Rose, 2010). For example, older adults who live alone are more likely to use an ambulatory device and have safety equipment, and also experience more falls (Elliott, Painter, & Hudson, 2009).

Environmental risk factors

Several environmental factors have been suggested to be related to falls in older people, namely, slippery or uneven floor surfaces, loose rugs and upended carpet edges, obstructed walkways, and poor building design, including raised door sills, inadequate stairs, and lack of handrails (Lord, Sherrington, Menz, & Close, 2007). Lord et al. (2007) suggest, however, that the existence of environmental risk factors for falls is not sufficient to cause falls. Rather, the interaction between the older adult's physical function, the perception of risk, and the exposure to the risk seems to be more important.

Relative importance of risk factors for falls

In the last decades, many investigators have conducted epidemiological studies to identify specific factors and their relative importance in increasing the likelihood of falling. In face of the large number of studies addressing this issue, some systematic reviews of literature were conducted and consistent conclusions advanced (Rubenstein & Josephson, 2002; Tinetti & Kumar, 2010; Deandrea et al., 2010). For example, Rubenstein and Josephson (2002) reported the results from a univariate analysis of multiple risk factors from 16 studies conducted in both community and nursing home environments. The authors identified 11 risk factors for falls as well as the relative risk (from prospective studies) or odds ratio (from retrospective studies) associated with each risk factor. Results from this review showed that the major risk factor for falls was muscle weakness, which was responsible for increasing the odds of falling over 4-fold on average (1.5–10.3). Having a history of falls, gait impairments, and balance deficits were also found to be significant risk factors in many studies, being associated with an approximately 3-fold increased risk of falling (RR/OR ranging from 1.7–7.0, 1.3–5.6, 1.6–5.4, respectively). Using an assistive device, having visual deficits and arthritis were associated with an approximately 2.5-fold increased risk of falling (1.2–4.6, 1.6–3.5, 1.9–2.9, respectively). Impaired ability to perform basic activities of daily living, depression, cognitive impairment, and age over 80 years were associated to a 2-fold increased risk of falling (1.5–3.1, 1.7–2.5, 1.0–2.3, 1.1–2.5). Since 11 of the studies included in this review used a multivariate analysis, accounting for the interaction between factors was important. The authors found, however, that the risk factors emerging from these analysis were similar to those identified in the univariate analysis, with slightly different sizes of risk for some of them. In the multivariate analysis, muscle weakness still remained the main risk factor with a 4-fold increased risk of falls. Balance deficits, a history of falls, cognitive impairment, age over 80 years, and visual impairments were associated with a 3-fold increased risk of falls, while gait impairments were associated with an approximately 2-fold increased risk of falls.

Tinetti and Kumar (2010) conducted a systematic review to identify multiple impairments and conditions predisposing community-dwelling older adults to falls. Of the 33 studies included, 17 risk factors were identified. Among the identified conditions, the strongest risk factors for falling, based on relative risk ratios (RR) were a history of falls (1.9-6.6), muscle weakness (2.2-2.6), balance deficits (1.2-2.4), gait impairments (1.2-2.2), and use of specific medications (1.1-2.4). Other common risk factors also included depression (1.5-2.8), dizziness or orthostasis (2.0), functional limitations and disability related to the performance of basic activities of daily living (1.5-6.2) and age over 80 years (1.1-1.3). Other risk factors only found in a small number of studies (two to three), were also identified by the authors. These included female gender (RR 2.1-3.9), low body mass index (RR 1.5-1.8), urinary incontinence (OR 1.3-1.8), cognitive impairment (RR 2.8), arthritis (RR 1.2-1.9), diabetes (RR 3.8); and pain (OR 1.7).

Similar results were described in a systematic review conducted by Deandrea et al. (2010). These authors analyzed a total of 74 studies and identified 31 risk factors, in older adults with a history of falls (single fall and reccurent falls). Results from this review showed that the factors most strongly associated with falls were a history of falls (OR 2.8 for all fallers; 3.5 for recurrent fallers), gait impairments (2.1; 2.2), use of walking aids (2.2; 3.1), vertigo (1.8; 2.3), Parkinson’s disease (2.7; 2.8), and use of antiepileptic drugs (1.9; 2.7). Unfortunately, the authors did not present odds ratios for balance deficits and muscle weakness, due to the heterogeneity of the measures used in various studies. Further evidence suggests that muscle weakness, balance and gait impairments, and the use of specific medications are the strongest modifiable risk factors for falls (Rubenstein & Josephson, 2002; Tinetti & Kumar, 2010; Deandrea et al., 2010).

In addition to discussing the relative importance of different types of risk factors for falls, the number of risk factors has also been shown to be important. In one study, the 1-year risk of falling increased linearly with the number of risk factors, ranging from 8% with none, to 78% with four or more risk factors (Tinetti, Speechley, & Ginter, 1988). Also, in a prospective study conducted by Muir et al. (2010a), when considering the impact of all risk factors together, fall risk doubled (RR 2.0; 1.13–3.56) per unit increase in the number of risk factors (e.g., lower-extremity muscle weakness, balance impairment, and four or more prescription medications). In the same study, the authors reported that lower-extremity weakness, balance impairment, and the number of risk factors were independent predictors of the transition in status from non-faller to faller. These results suggest the importance of the risk assessment and intervention targeting strength and balance also in older adults who have not yet fallen.

2.3. Balance in older adults

As previously discussed, falls in older adults are multifactorial in nature and impaired balance is one of the major factors associated with a higher risk of falling. From a rehabilitation nursing perspective, specifically in view of the "Functional consequences theory" (Miller, 2012), and considering the potential effects of prehabilitation exercise interventions on balance control, designing and implementing an effective balance intervention is the main topic of this research.

Balance

In the past decades, the scientific evidence of degeneration in balance control accompanying aging has led researchers and clinicians to look for a complete understanding of how balance control works (Winter, 1995).

In 1989, Nashner suggested that *human balance is maintained through a complex process involving sensory detection of body motions, integration of sensorimotor information within the central nervous system and execution of appropriate musculoskeletal responses* (p.5). Besides this definition gathers agreement, many other definitions and concepts have been used when discussing balance.

The term equilibrium is used to describe a body at rest - static equilibrium, or in stable motion - dynamic equilibrium (Kloos & Givens, 2012). Static equilibrium requires that the center of mass of the system be located vertically above the base of support, with zero velocity and all forces in all directions summing to zero (Chapman, 2008; Oatis, 2009). Yet, when considering human balancing, the requirement for static equilibrium is hardly applicable, due to the existence of the multi-segments of the body and the various forces acting upon them. The closest approximation to perfect static equilibrium is achieved by making small adjustments in joint positions in order to maintain a zero velocity.

Consequently, the position of the center of mass can move vertically or horizontally within the base of support, without the person falling (Chapman, 2008).

Though some authors refer to balance and postural stability as synonyms (Kloos & Givens, 2012), it has been argued that they do not refer exactly to the same concept (Haywood & Getchell, 2009). This position is supported by the idea that stability implies resistance to movement, while balance relates to the ability to maintain equilibrium, even when you are exposed to an unstable condition.

Limits of stability (LOS) is the term used to describe the distance that a person is able or willing to lean in a specific direction, without altering the base of support. While these limits vary according to the biomechanical characteristics of the individual, the type of task and environmental constraints, it has been demonstrated that an adult can sway approximately 12 degrees in the backward-forward direction and 16 degrees laterally without moving the feet (Nashner, 1989).

Individuals maintain or restore their postural control either consciously (i.e., anticipatory postural control) or subconsciously (i.e., reactive postural control) (Rose, 2010; Woollacott & Shumway-Cook, 1996). Anticipatory postural control can also be referred to as proactive postural control. It consists of the ability to activate postural adjustments in anticipation of potentially disruptive situations in order to minimize dislocation of the center of mass from its desired position (Woollacott & Shumway-Cook, 1996). It includes planned actions, such as obstacle avoidance or negotiation (Rose, 2010).

On the other hand, reactive postural control involves automatic responses to unexpected situations. These types of actions are executed when the sensory system identifies movement of the center of mass away from a stable position. In this situation, a muscle response is activated to rapidly restore the center of mass to a position of stability (Woollacott & Shumway-Cook, 1996).

Main motor strategies for postural control

In the past, disrupting stable equilibrium and observing the subsequent behavioral reactions has been a useful experimental approach for understanding the mechanisms of postural control (Horak, Henry, & Shumway-Cook, 1997). Horak and Nashner (1986) described three major postural strategies observed: (1) the ankle strategy; (2) the hip strategy; and (3) the step strategy. However, a variety of complex body movement trajectories can be generated by combining pure ankle and hip strategies, as acknowledged by these authors. In Horak and Nashner's experiment, when the participants were exposed to brief forward or backward horizontal surface perturbations in a standing position, a compensatory pattern of muscle activity was initiated within the ankle joint muscles. This level of muscle activity was sufficient to restore the individual's equilibrium. The authors termed this strategy the ankle strategy (Horak & Nashner, 1986). The ankle strategy can only be used to consciously control body sway in the standing position through a very small range on motion because the ankle joint muscles can only generate a relatively small amount of force. At a subconscious level, this strategy can also be used to restore balance following a small but unexpected perturbation. To be effective, this strategy demands an adequate range of motion and strength of the ankles, a firm and broad surface beneath the feet, and an adequate amount of sensory reception in the feet and ankles (Rose, 2010).

When facing a larger challenge, such as maintaining balance while standing on a surface that is narrower than the length of the feet, the leg and trunk muscles become active. This level of muscle activation, is referred to as the hip strategy (Horak & Nashner, 1986). In this strategy, the upper body moves in a direction that is opposite to the lower body to control postural sway as the larger hip muscles are activated. The effectiveness of this strategy is therefore dependent on an adequate range of motion and strength in the hip region (Rose, 2010).

Finally, if the center of mass is displaced beyond the limits of stability, one or more steps are needed to reestablish equilibrium. A new base of support must be established in this situation. This strategy is called the step or stepping strategy (Horak & Nashner, 1986). To be effective, the step strategy requires adequate lower muscle strength and power, range of motion, and adequate central processing speed (Rose, 2010).

The systems involved in balance control

Balance is a complex skill that involves the detection and integration of sensory information and the execution of appropriate motor and musculoskeletal responses to control body position that are specific to the environmental and task demands. This control mechanism demands the interaction of: (1) the sensory systems, (2) the motor system, and (3) the cognitive system (Rose, 2010; Winter, Patla, & Frank, 1990).

The peripheral and central components of the sensory systems

Three major sensory systems are involved in balance and postural control. They include the (1) visual; (2) vestibular; and (3) somatosensory systems (Horak, 2006; Kloos & Givens, 2012; Nashner, Black & Wall, 1982; Rose, 2010; Winter, 1995). It is the combination of the information received by the peripheral receptors of these three systems that will integrated by the central components of the sensory systems, and then allow the perception of one's body position and movement in space.

Vision is the system primarily involved in planning movement and negotiating or avoiding obstacles (Winter, 1995). This system provides information about the surrounding environment and our spatial location (Rose, 2010), and is derived from linear and angular motions of the visual field (Nashner, Black, & Wall, 1982). For example, the visual system can be used to promote postural stability, when the proprioceptive and vestibular inputs are unreliable, by fixating the gaze on a visual target (Kloos & Givens, 2012).

The somatosensory system is comprised of proprioceptive, joint, and cutaneous receptors (Kloos & Givens, 2012) that sense the position and velocity of the body segments, their contact with external objects and support surface, and the orientation of gravity (Nashner, Black & Wall, 1982; Winter, 1995). In contrast to the visual system, the somatosensory system provides information about spatial location and movement of the body in relation to the support surface and also about the relative position of body segments. In the absence of visual input, for example in dark environments, the somatosensory system is our primary source of sensory information to maintain balance (Rose, 2010).

The vestibular system is a balance mechanism located in the inner ear, which is activated when the head is moved (Rose, 2010). It senses sway-related linear and angular accelerations of the head, giving indications about the head's position and movement, in relation to gravitational and inertial forces (Nashner, Black & Wall, 1982; Winter, 1995). Pathways from the vestibular nuclei connect with motor pathways for postural control and coordination of eye and head movements. For example, the vestibulospinal reflex allows postural changes in response to body tilt and the vestibulo-ocular reflex stabilizes vision when the head is moving (Kloos & Givens, 2012).

For balance control, the central component of the sensory systems integrates the information received by the sensory systems, determines the body's spatial orientation (Horak, Henry, & Shumway-Cook, 1997; Rose, 2010).

Sensory organization allows the achievement of the two main goals of balance control: postural orientation and postural equilibrium. Postural orientation involves the active control of body alignment and tone with respect to gravity, support surface, visual environment and internal references, in response to the spatial orientation, which is based on the interpretation of the sensory information from somatosensory, vestibular and visual systems. Postural equilibrium, for instances, involves the coordination of sensorimotor strategies to stabilize the center of mass facing disturbances in postural stability (Horak, 2006).

The peripheral and central components of the motor system

The motor system has a major role to play in balance control through postural alignment and movement. Particularly, joint range of motion, joint integrity and muscle performance (strength, power and endurance) are important conditions to allow flexibility (Kloos & Givens, 2012).

For balance control, the central component of the motor system receives information from the central component of the sensory systems on the body's spatial orientation and generates the information for action to be executed by the motor system (Horak, Henry, & Shumway-Cook, 1997; Rose, 2010).

The cognitive system

Attention, memory and intelligence are important abilities that allow the individual to maintain balance. In connection to both the sensory and the motor systems, the cognitive system allows processing coordinated and accurate movements. Any impairment in cognition or lack of attention will compromise the ability to perceive the environmental demands and select the type of response needed (Rose, 2010). This demand for attention is easily seen when performing dual-task. When performing two tasks at a time, the individual has to divide attention and adapt his physical performance.

Age-related changes in the systems that contribute to balance

Research has shown that balance declines with aging. The greatest deterioration in balance and mobility occurs from 60 and 70 years onwards (Daly et al., 2013). Age-related changes, as described earlier when we introduced the "Functional consequences theory" (Miller, 2012), are inevitable, progressive, and irreversible changes that occur during late adulthood, affecting all body systems, including the systems that contribute to balance.

Therefore, the following discussion will address the age-related changes occurring in the peripheral and central components of the sensory and motor system.

In general, balance is affected when either the sensory systems, the cognitive system, or motor system is not working correctly or interaction among the systems is compromised (Browne & O'Hare, 2001). To the interaction of these systems, Kloos and Givens (2012) add the influence of contextual effects. These include the environment, which can be closed and predictable or open and unpredictable; the support surface, which can be firm or slippery, stable or unstable; the amount of light; the effects of gravity and inertia on the body; and the task characteristics, if it is a well learned or new task, planned or unplanned, single or multiple tasks.

Age-related changes in the sensory system

When sensory inputs contributing to balance control are reduced, older adults experience greater difficulty in maintaining balance (Woollacott & Shumway-Cook, 1990).

Structural changes in the eye, impaired proprioceptive function in eye muscles and poor retinal focusing are common age-related changes in the vision system (Shephard, 1997). Common effects of these changes include diminished visual acuity, depth perception and contrast sensitivity, and peripheral reduction in the visual field (Rose, 2010). Increased difficulty in judging distances, perceiving spatial relationships, and detecting low contrast hazards have a negative effect on maintaining balance and have been independently associated to falls (Lord, 2006). This overall degeneration in the visual system decreases or distorts information from the environment, which can be confusing or maladaptive for the older adult (Spirduso, Francis & McRae, 2005).

Although not caused by aging, but prevalent in a large percentage of older adults, certain diseases can intensify vision impairment. Very common eye diseases include cataracts, macular degeneration, and glaucoma that significantly compromise the quality of visual input (Miller, 2012). The wearing of multifocal glasses has also been shown to aggravate the effect of age-related changes. Specifically, near-vision lenses decrease depth perception, increasing the neglect of environmental hazards and therefore causing loss of balance and falls (Lord, 2006).

Age-related changes in the somatosensory system, particularly impaired proprioception, mainly in the lower limbs, have been associated with balance dysfunction in older adults. A diverse and non-uniform decline in sensory structures and function occurs with aging. Among these changes, there is a preferential loss in the anatomical structure and function of large myelinated fibers and associated receptors. This decrease is associated with impaired proprioception and/or vibration thresholds, and discriminative touch impairments (Shaffer & Harrison, 2007). Research has also shown that in older adults with increased instability, low proprioceptive control is associated with the deactivation of compensatory sensory and motor actions (e.g., visual stabilization, reactive postural control strategies) that adversely affect balance (Riva et al., 2013).

Gradual age-related changes in the vestibular system such as otoconial degeneration and loss of hair cells, also lead to increased sway and can be a potential cause of presbyvertigo. Studies have demonstrated that changes in shape and number of otoconia in the utricule and saccule (reduction) happen with increasing age. Additionally, age-related decreases in the number and density of hair cells, and increases in lipofuscin and other deformities in the cilia have been observed in human vestibular sensory and supporting cells (Walther & Westhofen, 2007).

The degeneration of nerve fibers, accompanies the decrease in the number of peripheral receptors and in their sensitivity to neurotransmitters (Shepard, 1997), which constitute the peripheral nervous system, and interfere with the quantity and quality of the information available to the central nervous system. Setti, Burke, Kenny and Newell

(2011) suggest that, since older adults rely more on multisensory processing for robust perception, the limits of the spatial and temporal window of integration become less fixed. As a consequence, irrelevant information can be integrated, leading to inefficient perception.

Age-related changes the motor system

In regard to skeletal muscle, atrophy appears to be inevitable with aging. A gradual loss of muscle fibres begins at approximately 50 years of age. By the age of 80, approximately 50% of the fibres are lost from the limb muscles (Faulkner, Larkin, Claflin & Brooks, 2007). Also, prospective research in older adults has demonstrated a consistent pattern of loss in grip strength from the age of 50 years (Daly et al., 2013), providing further evidence that the decline in muscle strength with aging accompanies the reduction in muscle mass (sarcopenia) (Spirduso, Francis & McRae, 2005). Associated with structural changes, older adults also exhibit lower muscle power than young adults.

Joint function is also affected by age (Hsu, Chou & Woollacott, 2013). Although similar patterns of joint movement and center of gravity excursion are observed in young and older adults during a reactive recovery response, in older adults, a larger proximal joint rotation induces a larger sway, contributing to inefficient posture recovery (Tsai, Hsieh & Yang, 2013). Corrective strategies for postural control are initiated later in older adults and often are disorganized, with both agonist and antagonist muscles being activated simultaneously, resulting in a general stiffening of the limbs (Shephard, 1997). For example, when using the hip strategy to prevent a loss of balance, older adults exhibit a reduced ability to use the thoracic-lumbar joint to compensate for the movement of the hip joint, contributing to instability (Hsu, Chou, & Woollacott, 2013).

Ankle strength also significantly declines with aging, affecting the plantarflexor muscles' role in supporting the weight of the body and providing stability at the ankle and feet when standing. The role of the dorsiflexor muscles in counteracting gravity during the swing phase of gait is also adversely affected. In addition, range of motion of the ankle joint, namely during eversion, is reduced, contributing to increased sway (Kok, Lee, & Lee, 2013).

Age-related changes also influence gait variability. Gait variability, meaning stride-to-stride fluctuations, is linearly increased with age and is considered a marker for gait performance and future mobility status, cognitive status, and falls (Callisaya, Blizzard, Schmidt, McGinley, & Srikanth, 2010; Maki, 1997). Overall, research has shown that older adults adopt a gait pattern that is characterized by a reduced step velocity and stride length when compared to young adults, particularly during obstacle avoidance (Lowrey, Watson, & Vallis, 2007; Menz, Lord, & Fitzpatrick, 2003). In general, a slower gait speed among older adults has been associated with age-related changes in the various systems that contribute to balance. Yet, age-related decline in leg strength seems to be the primary factor contributing to reduced gait speed (Menz, Lord, & Fitzpatrick, 2003; Studenski et al., 2011; Wood et al., 2009).

Age-related changes in the cognitive system

Also, age-related changes in the central nervous system affect cerebral function. Analyzing previous research, Grady (2008) described similarities in the patterns of brain activity in young and old adults, indicating that basic neural mechanisms are maintained during aging, despite the existence of structural changes in the central nervous system (e.g., decline of grey and white brain matter). However, older adults often have less activity in the medial temporal areas during memory processing. In addition, in face of these changes, the older adult seems to use, as a compensatory strategy, the over-recruitment of some brain areas during memory tasks and cognitive control processes.

Among age-related changes that happen in the cognitive system, there are disturbances in attention, memory and intelligence. Therefore, the older adults may present reduced ability to anticipate and adapt to changes in the environment (Rose, 2010).

A systematic review of the scientific evidence emerging from longitudinal studies addressing the relationship between physical and cognitive functioning, indicated an association between the changes in physical and cognitive functioning. However, because not all declines occur together, the association was not sufficiently strong and consistent enough to provide conclusive evidence for “common cause” aging (Clouston et al., 2013). This new evidence again highlights the importance of activity or intervention in preventing physical and cognitive decline in older adults.

Age-related changes in the central nervous system affect central processing functions, conditioning sensory inputs and outputs. Effects of these changes are seen in other systems and include decreased motor response and cognitive impairments (Shephard, 1997; Madhavan & Shields, 2005). In summary, studies have identified several changes that affect the various mechanisms of balance and postural control as age advances, and these contribute to reduced mobility and stability in older adults (Noohu, Dey, & Hussain, 2013).

Balance assessment in older adults

Balance can be assessed at a physiological and/or functional level. Physiological assessments focus on measuring the relative contributions of each body system that contribute to balance, while at the functional level, more functional performance tests of balance and mobility are administered (Browne & O’Hare, 2001). This latter approach includes indirect clinical measures of balance. In contrast to direct measures of balance, such as force platform assessments, these do not require expensive equipment and are easy to use in community settings (Howe et al., 2011). However, while physiological tests can be used to identify the underlying impairments that contribute to poor balance, functional performance tests can only be used to identify functional limitations.

In a recent systematic review of literature addressing balance assessment in for community-dwelling older adults, 26 different measures were identified (Pardasaney et al., 2013). Eight single item measures were found: (1) the four-square step test [FSST]; (2) the functional reach test [FRT]; (3) the turn 180 degrees test; (4) the single-leg stance test [SLS]; (5) the tandem stance test; (6) the tandem walk; (7) the Romberg test; and (8) the step test. Five measures included multidirectional assessments of leaning, stepping, or reaching tasks: (1) limits of stability measure [LOS]; (2) maximum step length [MSL]; (3) the rapid step test [RST]; (4) the multidirectional reach test [MDRT]; and (5) the lateral reach test [LRT]. Five other tools were multi-item scales, addressing different dimensions of balance: (1) the Berg balance scale [BBS]; (2) the mini-balance evaluation systems test [MiniBESTest]; (3) the Fullerton Advanced Balance scale [FAB]; (4) the Performance Oriented Mobility Assessment balance scale [POMA-B]; and (5) the frailty and injuries: cooperative studies intervention techniques 4 [FICSIT-4]. Three measures addressing various systems that contribute to balance: (1) the Dynamic Balance Assessment [DBA]; (2) the Sensory Organization Test [SOT]; and (3) the Clinical Test of Sensory Interaction in Balance [CTSIB]. Two measures addressed mobility: (1) the Sensory-Oriented Mobility Assessment Instrument [SOMAI] and; (2) the Functional Obstacle Course [FOC]. Two other measures assessed gait: (1) the Functional Gait Assessment [FGA] and (2) the Dynamic Gait Index [DGI]. Finally, one measure focused on dual-task balance assessments: (1) the Multiple Tasks Test [MTT]. The results from this review showed that the existing measures of balance are often limited to single-task assessments in static environments, disregarding the real balance demands associated with daily living activities. The item-level content analysis of each balance measure led the authors to conclude that a single measure encompassing all relevant content areas was not found. Nevertheless, the most comprehensive assessment tools were determined to be the Mini-BESTest and the FAB scale.

In a previous review of literature, in which attention was restricted to functional balance assessment in community-dwelling older adults, the FAB scale was identified as one of the most complete, reliable, and valid balance assessment tools, together with the BBS. Nevertheless, the FAB scale was noted to include sufficiently challenging test items that made the assessment more appropriate for use with independently living older adults, while the BBS is more appropriate for use in frail people (Langley & Mackintosh, 2007).

Since the present research focuses on assessing balance in independent, community-dwelling older adults and easy reproducibility in rehabilitation nursing clinical practice is desired, the Fullerton Advanced Balance scale will be used in our trial, as the main outcome measure. Because of this greater attention will be given to this tool in this section.

The FAB scale is a multidimensional balance assessment tool that is designed to be used when assessing the balance of higher functioning older adults. This test was primarily developed by Debra Rose at California State University, Fullerton (Rose, Lucchese, & Wiersma, 2006).

The FAB scale is a performance-based measure that comprehensively addresses the multiple dimensions of balance, through static and dynamic balance activities performed in different sensory environments. The scale includes 10 individual test items, which are scored using a 5-point ordinal scale (0–4). The maximum score on the FAB scale is 40 points. This assessment can be conducted in a relatively small area and its administration requires approximately 10 to 12 minutes. The necessary equipment includes a stopwatch, a pencil, a 12-inch ruler, a 6-inch-high bench (15.2cm), masking tape, two foam pads 2.5-inch-high (6.4cm), a yardstick, and a metronome. The FAB scale is comprised of the following test items: (Item 1) standing with feet together and eyes closed; (Item 2) reaching forward to retrieve an object; (Item 3) turning in a circle; (Item 4) stepping up and over a bench; (Item 5) tandem walking; (Item 6) standing on one leg; (Item 7) standing on foam with eyes closed; (Item 8) jumping for distance; (Item 9) walking with head turns; and (Item 10) recovering from an unexpected loss of balance. A full description of the FAB scale and specific instructions for test administration are published and available for further reading (Rose, 2010).

Preliminary results of the psychometric evaluation of the scale's content, its convergent validity, test-retest, and intra- and inter-rater reliability, and also internal rater consistency were first published in 2006 (Rose, Lucchese, & Wiersma, 2006). The validation process took in account several procedures. The content validity was based on results from a review of literature, an expert panel examination and feedback, and pilot-testing of the original scale with 15 healthy, older adults. Convergent validity was obtained by comparing results with the BBS assessment in 31 participants. The results of the Spearman rank correlation analysis indicated a significant ($p=0.01$) and moderate correlation of 0.75 between total scores of both scales. The results from this study also showed that the test-retest reliability coefficient for the total scale score was 0.96. The inter-rater reliability coefficients for the total score ranged from 0.94 to 0.97, while the intra-rater reliability ranged from 0.97 to 1.00. The homogeneity coefficients (H) were greater than 0.90 for six of the test items and all 10 test items had H coefficients of greater than 0.75 for both rating sessions. Despite stating the use of retrospective data as a limitation of the study, the authors were able to conclude that the FAB scale is a valid and reliable assessment tool that it is suitable for use with functionally independent older adults residing in the community.

More recently, the psychometric properties and dimensionality of the FAB Scale were further evaluated by Klein, Fiedler, and Rose (2010). A Rash analysis of the scale was conducted by these authors in a sample of 480 community-dwelling adults, aged 60 years and older who were able to ambulate independently. This approach allowed the authors to verify that the reliability of the scale to separate persons was 0.81 out of 1.00 and the reliability of the scale to separate items in terms of their difficulty was 0.99 out of 1.00. Two construct domains were identified. Specifically, nine of the 10 test items were related within one construct domain, while item 10 (reactive postural control) was independent. However, the Cronbach's alpha value of 0.805 was found for the total FAB scale, confirming its good internal consistency.

Research has also been conducted to determine if the FAB scale is predictive of faller status in independently functioning older adults (Hernandez & Rose, 2008). In this study, a cross-sectional design was used to establish the sensitivity and specificity of the FAB scale to predict faller status (defined as persons with a history of 2 or more falls in the previous 12 months) based on a retrospective self-reported fall history. Results from this study indicated that the total FAB scale score could be used to predict faller status. The cut-off score of 25 out of 40 on the FAB scale produced the highest sensitivity (74.6%) and specificity (52.6%) in predicting faller status. Moreover, the probability of falling increased by 8% with each 1-point decrease in total FAB scale score. This allows a clinician to draw the conclusion that an older adult who scores 25 or lower on the FAB scale is at high risk for falls and in need of immediate intervention. In addition, the scale can be used to monitor balance and fall risk among older adults in clinical and community contexts.

Exercise interventions to improve balance of older adults

Due to the association that exists between balance impairments, reduced physical functioning, and increased risk of falling in older adults, research has been conducted to analyze the effects of exercise interventions on balance (Howe et al., 2011). Specifically, the effectiveness of community-based group-structured exercise programs has been extensively studied over the past 20 to 25 years (Rose, 2008), allowing the scientific community to draw some conclusions on this topic. Nowadays, there is scientific evidence that specific exercise can improve balance and also reduce falls in older people (Gillespie et al., 2012; Howe et al., 2011; Sturnieks, St George & Lord, 2008).

In a recent update of a Cochrane review, Howe et al. (2011) examined the effect of different exercise interventions on balance in older adults, aged 60 and over, and living in the community or in institutional care setting. This review included 94 randomized controlled trials, with a total of 9917 participants, predominantly women, living in community settings. Most of the studies were small, and included different proportions of men and women. Only 25 studies included more than 100 participants at entry, 20 had less than 40 participants and the smallest study included 14 participants at entry. Primary outcome measures included: (1) the timed up & go test; (2) standing on one leg for as long as possible with eyes open; (3) standing on one leg for as long as possible; (4) gait speed; (5) the BBS; and (6) adverse events associated with the exercise intervention.

In the same review, different intervention types were identified and categorized into eight categories: (1) gait, balance, co-ordination, and functional tasks; (2) strengthening exercise; (3) three-dimensional exercise (3D); (4) general physical activity – walking; (5) general physical activity – cycling; (6) computerized balance training using visual feedback; (7) vibration platforms; and (8) multiple exercise types. The results of this review provided evidence for some types of exercise when compared to a usual activities group while also demonstrating moderate improvements in clinical balance outcomes in older adults, immediately after the intervention. The greatest improvements in indirect clinical balance outcomes were found for exercise programs including gait, balance, coordination and functional tasks; strengthening exercise; 3D exercise, and multiple exercise types. There was insufficient evidence to draw any conclusions about the effectiveness of interventions that included general physical activity (walking or cycling), exercise involving computerized balance programs or the use of vibration plates. Also, duration and frequency of the interventions were also heterogeneous; nevertheless, the most effective programs were conducted at least three times a week, for at least three months. Because most studies lacked long-term follow-up, there was no evidence of lasting effects after the exercise intervention ceased, suggesting that positive balance effects are only evident while engaged in the intervention. Other limitations of the studies reported in the review included such things as potential bias and lack of details of the study protocol.

In conclusion, Howe et al. (2011) state that further high quality methodological research using core outcome measures and adequate surveillance is necessary to provide more robust evidence on this topic.

With different purposes, another review addressed the influence of exercise on falls and fall risk reduction in community-dwelling older adults and presented a synthesis of outcome measures for the assessment of fall risk in community-dwelling older adults (Arnold, Sran & Harrison, 2008). This review included 22 randomized controlled trials.

Results from this review confirmed that the number of falls and fall risk can be reduced with exercise interventions in the community-dwelling older adults, delivered either in a group, individually, or in a combined format. No conclusions were possible to draw on the optimal type, frequency, and dose of exercise to achieve a positive effect however, due to the heterogeneity of the studies included. In regard to the measures of fall risk used, a wide variety were found and categorized. These included: (1) muscle strength; (2) functional tasks (e.g., timed up & go test); (3) balance measures; (4) gait parameters (e.g., velocity); (4) fear of falling or falls efficacy; (5) self-reported functional status; and (6) a composite measure of several physiological factors resulting in a fall risk score. The use of multiple outcome measures suggests that no single tool is currently available that optimally predicts faller status. The authors highlight, however, that since impaired balance is a key risk factor for falls, selecting the most comprehensive measure of balance is important when evaluating patients at risk of falling.

These findings are in agreement with the conclusions of other reviews focused on the effects of interventions to reduce falls. Collectively, the findings suggest that exercise can lower fall risk and/or decrease fall rates (Balzer, Bremer, Schramm, Lühmann, & Raspe, 2009; Costello, & Edelstein, 2008; Gillespie et al., 2012; Sherrington, Tiedemann, Fairhall, Close, & Lord, 2011).

2.4. The ProBalance intervention

This subchapter aims to describe concisely the theoretical background to the ProBalance intervention and give a general understanding of its components.

This intervention is an exercise program designed to address balance of independent-living older adults with balance impairments. It is inspired by the FallProof Balance and Mobility Program (Rose, 2010) and by the programs implemented in the Center for Successful Aging - California State University Fullerton, through the collaboration of the expert in the field, Professor Debra Rose.

Such as in the Fallproof Program, this intervention intends to respond to the need for effective programs that target the important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness. It is a theory-driven program, adopting a multidimensional approach to balance and mobility in older adults identified as moderate-to-high risk for falls (Rose, 2011).

The ProBalance intervention is structured in 24 unique sessions, implemented by a rehabilitation nursing specialist. These sessions are planned in a group basis, with 90 minutes duration, 2 days per week, during 12 weeks. The level of challenge of the sessions were progressively higher, however, individualization was possible by manipulating the level of challenge associated with each set of progressions presented to the group.

Basis for the program

Previous randomized controlled trials have shown that the greatest improvements in indirect clinical balance outcomes are associated to exercise programs including gait, balance, co-ordination and functional tasks training; strengthening exercise; 3D exercise and multiple exercise types, as it was verified in the systematic review developed by Howe et al. (2011). Taking into account these results and referring to the same terminology, the ProBalance is a multiple exercise types program, including exercises that fit the following categories: balance, co-ordination and functional tasks training, gait training, strengthening and flexibility exercises and 3D training.

However, in our work, the terminology used to describe the components of the ProBalance exercise program is the one used in the FallProof program (Rose, 2010), as it was the main inspiration for the development of this intervention.

The exercise intervention included six key components, which will be further addressed: (1) center of gravity control training; (2) multisensory training; (3) postural strategy training; (4) gait pattern enhancement and variation training; (5) strength and endurance training; and (6) flexibility training.

Center of gravity control training

Center of gravity control training aims to improve the older adult's ability to maintain body alignment in the upright and in the seated position; to lean and return to a central position and to move the body fast and confidently. In a variety of exercise, the older adults is oriented to move his center of gravity over the base of support, progressing from the seated to the upright position and then to moving tasks, the challenge is increased gradually (Rose, 2010).

Multisensory training

Multisensory training addresses the visual, vestibular and somatosensory systems, aiming to optimize the functioning of the unimpaired sensory systems and compensate for the systems that are known to be permanently impaired. This component includes exercises designed to improve the functioning of the somatosensory system by reducing or removing visual inputs; to improve the use of vision by manipulating the somatosensory inputs; to improve vestibular system function by manipulating both the visual and somatosensory systems; and to enhance the coordination between the visual and the vestibular systems. All older adults, even older adults that show good sensory reception and integration skills, benefit from engaging in sensory stimulation activities, counteracting the age-related changes known to affect the sensory systems. However, in face of sensory impairments, two strategies are incorporated in the training: (1) the forced use of an impaired sensory system, when the impairment is temporary or changeable and (2) the forced use of the other systems in order to compensate or substitute a permanently impaired system (Rose, 2010).

Postural strategy training

According to Rose (2010), postural strategies training can be done by manipulating the task and the environment, to enable the older adult to practice the ankle, hip and step strategies. Three main approaches are mentioned by the author: (1) standing on different support surfaces; (2) voluntarily swaying through an increasingly larger distance in multiple directions, when standing in different support surfaces; and (3) controlling postural sway in response to progressively stronger applications of external forces. Training progression is done from the ankle strategy, to the hip strategy and the to the step strategy. This type of training, at a conscious level, aims to develop the older adult's ability to respond to expected or unexpected events with efficient proactive and reactive postural strategies.

Gait pattern enhancement and variation training

An efficient, flexible and adaptable gait pattern is required for successful and safe locomotion in different environments, with specific timings and spatial demands, and changing tasks. Referring to gait pattern enhancement and variation training, Rose (2010) describes five strategies: (1) walking with directional changes and sudden starts and stops; (2) walking with an altered base of support; (3) varying the gait pattern (side stepping, braiding, tandem walking); (4) obstacle negotiation or avoidance; and (5) gait pattern enhancement and variation obstacle course. In overall, this set of progressive gait activities are designed to enhance gait pattern and give the older adult the ability to change postural orientation, in response to environmental demands.

Strength and endurance training

Postural alignment, balance and good mobility require adequate muscle strength and endurance. Therefore, Rose (2010) suggests that a balance and mobility program should include activities that increase strength and power, both in the upper-body and lower-body. In addition, the author highlights the importance of incorporating strength and power exercises in a balance environment. Materials such as resistance bands, weighted balls and hand weights are used in this training component, allowing progressions from less resistant or less heavy to more resistant or heavier.

Flexibility training

Flexibility exercises target the improvement in the range of motion of joints and muscles in the upper and lower-body, which are necessary for good balance and mobility. Rose (2010), recommends that dynamic stretching activities are suitable for warm-up period and static stretching activities are more adequate for the cool-down period.

Further explanation on the procedures of the implementation of this intervention will be given in the methods section of this thesis.

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Chapter 3

Method

3.1 Study type
3.2 Investigation question
3.3 Sample and participants
3.4 Eligible participants
3.5 Recruitment and enrolment
3.6 Intervention and control
3.7 Outcome and interfering variables
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Bridge

In this chapter, detailed information is given on the research methods in our project. This section will address in a concise way the general information on the subjects, the instruments and procedures, aiming to describe the research process underlying this thesis. This information will be complemented with specific information for each study in the research reports that will be presented in the subsequent chapters.

3.1 Study type

This research comprised two studies. The main study in this project is a randomized controlled trial (RCT), with parallel groups and repeated measures, focused on the effect of a non-pharmacological treatment for balance declines in community-dwelling older adults, namely, a rehabilitation nursing intervention targeting community-dwelling older adults screened and identified with balance impairments.

This RCT was prospectively registered in the Australian New Zealand Clinical Trials Registry Platform and the clinical trial registration number was ACTRN12612000301864. Therefore, information about the study protocol is available online in the World Health Organization International Clinical Trials Registry Platform (see http://apps.who.int/trialsearch/Trial.aspx?TrialID=ACTRN12612000301864).

Methodological options in the design of this research, as well as the report of our investigation, took into account the Medical Research Council guidance for the development, evaluation and implementation of complex interventions to improve health (MRC, 2008), as well as the previously mentioned CONSORT Statement (Boutron et al., 2008), as a guideline for reporting results from clinical trials.

This main RCT was preceded by a small scale pilot RCT, developed to test feasibility of the ProBalance program and allow the modelling of this research. The development of the pilot study will be further discussed later in this chapter, in the quality control section.

3.2 Investigation question

This research was based on the following investigation question: What are the effects of the ProBalance program (a gerontological rehabilitation nursing program) in a group of community-dwelling older adults, specifically, on their balance, muscular strength, and gait?

3.3 Sample and participants

The sample of this RCT consisted of 177 relatively healthy community-dwelling men and women aged 65-85 years old.

The optimal sample size was determined based on previous research and the results of our pilot study (4-week duration Mini-RCT), using G*Power3 (Faul, Erdfelder, Lang, & Buchner, 2007). A priori, repeated-measure ANOVA indicated that a total sample size of 48 was needed to achieve 95% power to detect the interaction effect size of 0.25 at the 0.05 level of significance. Although 0% attrition rate was found in the Probalance pilot study, a potential 8% attrition rate was considered for the main RCT and a total of 52 participants were targeted in this study.

3.4 Eligible participants

The participants were relatively healthy volunteers of both genders.

The key inclusion criteria were: (1) to be community-dwelling older adult, aged 65 to 85 years old; (2) presenting a FAB score higher than 25/40 and equal or lower than 30/40, or to present a FAB score between 20 and 25/40, if not reporting falls in the last year; and (3) being able to walk independently.

The key exclusion criteria were: (1) to present cognitive impairment [(assessed by the Mini Mental State Test (MMST)], and (2) to have any significant co-morbidities that could preclude participation (acute illness, progressive neurological disease, stroke, unstable chronic conditions).

3.5 Recruitment and enrolment

Participants were recruited from Madeira, Funchal, by advertising in a regional newspaper, posters, flyers with written information and social networks, as well as through presentations by the responsible researcher to religious communities and social institutions in the city. Advertisement started in January 2012. Recruitment started in March 2012 and was completed in April 2012. The volunteers were received in the project's laboratory and the assessments on inclusion and exclusion criteria were done, after informed consent.

After the first selection of those with inclusion criteria, participants were randomized and allocated to the groups, and the baseline assessments were done. A simple randomization process, using computer random number generator, was used to allocate the participants to one of the two similar groups (1. treatment and 2. control group). Numbers were randomly selected to form group 1 and group 2, using a random number generator software (Microsoft Excel 2010). This procedure was done and recorded by an independent person, who was not part of the project's research team. Also, the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, to which group the subject would be allocated. Clusters were only considered in the randomization, for couples and relatives.

3.6 Intervention and control

The predictor variable in this project is the intervention – the ProBalance program – a rehabilitation nursing intervention. Following the baseline assessment of all studied variables, this multidimensional rehabilitation nursing intervention was delivered to the intervention group (IG).

This intervention comprises a multiple risk approach, namely, an exercise program (tailored for older adults with moderate to high risk for falling) and an educational component aimed to enhance participant's adherence to the intervention program, addressing fall prevention.

The exercise sessions included: (1) multisensory training (approaching visual, somatosensory and vestibular systems); (2) center of gravity control training; (3) proactive and reactive postural strategy training; (4) gait pattern enhancement and variation training; (5) strengthening and endurance training; and (6) flexibility training. It was structured in 24 unique sessions, as in the planning in attachment (Appendix I). These rehabilitation sessions had a 90 minutes duration, 2 days per week, during 12 weeks uninterrupted weeks (between April and July 2012).

The intervention was based in the *FallProof Program*, which is a program designed and implemented by Professor Debra Rose, Director of the Center for Successful Aging, California State University Fullerton. Likewise, the ProBalance is a theory-driven program, adopting a multidimensional approach to balance and mobility in independent-living older adults with balance impairments. It targets important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness (Rose, 2011).The rationale for the development of this exercise intervention is described in the review of literature. Further explanations can be found in the FallProof book (Rose, 2010), which supports this type of approach to balance in older adults.

The educational component is also documented in Appendix II, as a session plan. The two educational sessions were delivered in the beginning and in the middle of the intervention, with 45 minutes duration each. This component addressed general aspects of fall prevention (risk factors and consequences of falls in older adults and importance of motivation in the adherence to fall-prevention interventions).

The whole intervention was administered on a group basis, by only one trained rehabilitation nurse specialist, who had, in the context of this education cycle, a period of learning in the Center for Successful Aging, California State University Fullerton, under Professor Debra Rose's supervision. Besides this specific and practical training, this nurse has also a 9 years working experience in community nursing and nursing education and has developed and participated in several projects focused in the care of older adults.

In addition, in the ProBalance sessions, there were other independent members of the intervention team (trained university students) that assisted in the exercise preparation and kept security conditions next to the older adults during exercise performance (1:1 ratio).

In this RCT, the control was a waiting list control group (CG). This way, the CG received no intervention, only assessments and standard/usual care during the trial. After the end of the follow up period, the intervention was available for the CG, due to ethical issues.

3.7 Outcome and interfering variables

The central dependent variable or main outcome variable in this study was clinical balance, assessed by a multidimensional scale – The Fullerton Advanced Balance (FAB) scale. Secondary outcomes were strength of the lower body, strength of the upper body and gait parameters at preferred and maximal speed, particularly gait velocity, stride length and cadence.

Other variables were also considered in this study, as they can interfere with the outcome. Among these variables, this project included other functional fitness components, fear of falling, health-related quality of life, physical activity, cognition, number of fallers and total number of falls.

3.8 Instruments and assessments

All the assessments took place in the ProBalance Laboratory, in University of Madeira. To maximize the consistency of assessment procedures, measurements were conducted by six registered Nurses and an expert in the field of gerokinesiology, who coordinated the assessments and gave specific training prior to the trial (12 hours). The same research members took the measurements under similar conditions. At the baseline, all the measurements and protocols were theoretically presented as part of the training. In a second phase, all the measurements and questionnaires were applied between the members of the field team. In addition, training sessions were extended to a group of older adults belonging to a physical activity program.

In all measurement process during the RCT, the participants were assessed by blinded and independent assessors. The time points for assessment were at 0 (pre-test), 12 (post-test), and 24 weeks (follow up). Prior to this RCT and after specific training, test-retest reliability of the assessments was established in the pilot study (12 participants, 2 assessments with 1-week interval). The questionnaires and record sheets for physical tests were compiled in an individual file, which is presented in Appendix III.

Balance measured by the Fullerton Advanced Balance (FAB) Scale

The Fullerton Advance Balance (FAB) scale is designed to measure changes in multiple dimensions of balance and mobility in independent functioning community-dwelling older adults. The FAB scale includes a combination of static and dynamic balance activities performed in different sensory environments. The scale comprises 10 items, namely: standing with feet together and eyes closed (item 1), reaching forward to retrieve an object (pencil) held at shoulder height with outstretched arm (item 2), turning 360 degrees in right and left direction in a circle (item 3), stepping up and over a 15 cm bench (item 4), tandem walking (item 5), standing on one leg (item 6), standing on foam with eyes closed (item 7), jumping for distance (item 8), walking with head turns (item 9), and recovering from an unexpected loss of balance (item 10). Each item is scored on an ordinal scale ranging from 0 to 4 points. The maximum possible score for the FAB scale is 40 points. Further details referring to the protocols of administration, equipment and an explanation about static and dynamic balance activities are described in Rose (2003) and Rose (2010).

Strength and other functional fitness components measured by Senior Fitness Test components

Strength (upper and lower body) was part of the Senior Fitness Test (SFT) assessment. This fitness test battery was developed by Rikli and Jones (1999a, 1999b) and it is appropriate for older adults, since it reflects the major physical parameters associated with functional mobility. This battery includes measures of upper - and lower body strength and also flexibility, aerobic endurance, dynamic balance and agility, height and weight.

To minimize the effects of fatigue, stations were arranged in the following order: chair stand test (lower body strength), arm curl test (upper body strength), chair sit and reach test (lower body flexibility), back scratch test (upper body flexibility), 8-foot up-and-go test and (agility/dynamic balance). The 6-minute walk test (aerobic endurance) was administered after all other tests and questionnaires had been completed. All participants received the same instructions about the procedures of each test and they completed one or two trials to become familiarized with the task. A detailed description of the evaluation procedures, namely, equipment, procedure, scoring and safety precautions can be found in the SFT manual (Rikli & Jones, 2001). The anthropometric measures were obtained according to the standardized procedures described by Claessens et al. (1990). Height was measured with a Harpenden stadiometer (Holtain Ltd.). The measures were recorded to the nearest millimeter. Body mass was measured on a balance-beam scale accurate to 0.1 kg (Seca Optima 760, Hamburg, Germany). Participants wore light, indoor clothing without shoes and jewelry during the measurements. Measurements were performed twice and a third measurement was carried out in case of excessive difference. The scores of the two or the two closest measurements were averaged to reduce measurement error.

Gait parameters measured by the 30-foot (9 m) walk test at preferred and maximum speed

The 30-foot (9 m) walk test is a useful measure to assess gait speed and the indication of whether an older adult is able to adapt their gait speed to accommodate a change in task demands. We also used this test in our study to identify functional limitation in mobility. Participants were required to walk a total distance of 50 feet (15 m), first at a preferred speed and then at a maximal speed, and the distance between 10 and 40 feet (3 and 12 m) was timed for the purpose of calculating gait velocity (GV) and other measures of gait. The number of steps was counted over the same 30 feet (9 m) distance, in order to calculate cadence (steps per second) and stride length (SL) (SL = divide number of steps by 2 to get the number of strides, and then divide 30 feet (9 m) by the number of strides to get the SL) (Rose, 2010). The gait stability ratio (GSR) is calculated from cadence and velocity and expressed in units of steps per feet (GSR is the ratio of cadence to velocity expressed in units of steps per foot meter) (Cromwell, & Newton, 2004). This last measure is a measure of gait stability, with higher values indicating more time spent with the feet in contact with the ground during the gait cycle. A full description of test administration instructions for 30 foot (9 m) walk test at preferred and maximum speed is reported by Rose (2010).

Fear of falling measured by the Falls Efficacy Scale

The Falls Efficacy Scale (FES) (Tinneti, Richman & Powell, 1990) was used to measure the fear of falling. The FES is a widely used, reliable, and valid criterion measure of fear of falling in Portuguese population (Melo, 2011).

FES assesses an individual’s perceived confidence that the elderly present at the completion of 10 relevant and common activities, such as: (1) dressing and undressing; (2) prepare a light meal; (3) taking a bath or shower; (4) sitting/lift chair; (5) lying/get out of bed; (6) answer the door or the phone; (7) walking into the house; (8) reach for shelves; (9) light housework; (10) small purchases. The confidence that the elderly have to carry out the activities without falling, is represented in an analog 10-point scale ranging from "No confidence" (10 points) to "Completely confident" (1 point). The score of the FES is the sum of the scores obtained in each of the 10 items. The minimum score possible is 10 and the maximum is 100, meaning that the lower is the score, the greater the trust, translating into high self-efficacy.

Health-related quality of life measured by the Medical Outcomes Survey Short Form-36

Health Related Quality of Life (HRQOL) is the perception by the individuals regarding their position in life, in the context of their culture and value systems, and in relation to their goals, expectations, standards, and concerns (WHO,1993). The Medical Outcomes Survey Short Form-36 (MOS SF-36) questionnaire was administered in our study to assess HRQL (Ware & Sherbourne, 1992).The MOS SF-36 is a widely used, reliable, and

valid criterion measure of HRQL in numerous populations, including in Portuguese people (Ribeiro, 2005).
The MOS SF-36 questionnaire has 36 questions that are scored to measure eight domains of HRQL pertaining into two-components: a Physical Component and a Mental Component (Ware & Sherbourne, 1992). The Physical Component comprises: (i) physical functioning, (ii) role-physical (role limitations due to physical health problems), (iii) bodily pain, and (iv) general health. In relation to Mental Component, are included: (i) vitality, (ii) social functioning, (iii) role-emotional (role limitations due to emotional problems), and (iv) mental health. Each domain was scored using a scale ranging between 0 and 100, with higher scores indicating a higher HRQL than lower scores. Finally, scores were summarized into two components, namely physical and mental.

Cognition, assessed by Mini-mental State Test

The Mini-Mental State Examination (MMST) (Folstein, Folstein & McHugh, 1975) was used to measure the mental state. The MMST is a widely used, reliable, and valid criterion measure that provides information on different cognitive parameters, containing questions grouped into seven categories, each designed to evaluate cognitive "functions" as a specific orientation to time (5 points), spatial orientation (5 points), registration of three words (3 points), attention and calculation (5 points), recall of three words (3 points), language (8 points) and visual constructive ability (1 point). The MMST score can range from a minimum of 0 points, which indicates a higher degree of cognitive impairment of individuals, up to a maximum total of 30 points, which, in turn, corresponds to better cognitive ability.
The MMST questionnaire was validated in the Portuguese population by Guerreiro et al. (1994). The cut-off points defined by Guerreiro et al. (1994) was used in the present study to detect cognitive impairment (without education ≤ 15 points; 1-11 years of education: ≤ 22 points; and higher than 11 years of education: ≤ 27 points).

Physical activity measured by the Modified Baecke Questionnaire

Habitual physical activity was assessed during face-to-face interviews using the modified Baecke Questionnaire developed in the Netherlands (Voorrips, Ravelli, Donelmans, Deurenberg & Staveren, 1991). The participants were asked to report habitual physical activities with a reference time period of last year. This questionnaire includes three specific domains: household activities, sport activities, and other physically active leisure time activities. Items on household activities are questions with four to five possible ratings, ranging from very active to inactive. Sports and other activities are asked as type of activity, hours per week spent on it, and period of the year in which the activity is normally performance. All activities are classified according to work posture and movements. An intensity code, originally based on energetic costs was used to classified each activity (Bink, Bonjer, & Sluys, 1966). A detailed description of the scoring procedures for calculation of habitual physical activity and its subcomponent categories (household activities, sport activities, and other physically active leisure time activities) is provided by Voorrips et al. (1991). The questionnaire took about 20 minutes to complete.

Number of fallers and total number of falls assessed by the health history questionnaire

Demographic information and a complete health history were assessed during face-to-face interviews. A modified version of the health questionnaire employed in the FallProof! Programme (Rose, 2003) was used to assess information about pathology/disease and lifestyle characteristics. The section of pathology/disease included: diagnosis of pathologic condition (heart attack; transient ischemic attack; angina; high blood pressure; stroke; peripheral vascular disease; diabetes; neuropathies; respiratory disease; Parkinson's disease; multiple sclerosis; polio/post-polio syndrome; epilepsy/seizures; other neurological conditions; osteoporosis; rheumatoid arthritis; other arthritis conditions; back problems, visual/depth perception problems; inner ear problems/recurrent ear infections; cerebellar problems; chemical dependency; depression); cancer; joint replacement, cognitive disorders, uncorrected visual problems, and other type of health problem. The information about lifestyle characteristics included: information about symptoms in legs or feet (numbness, tingling, arthritis, and swelling); eyeglasses (eyesight was checked at least once a year); hearing aids; assistive device for walking; the list of all medication that participants currently took (including all over-the-counter and alternative medicines). Specific questions about life events was also asked to participants, including: emergency medical care or hospitalization in last year; condition or injury that has affected balance or ability to walk without assistance; falls in the last 6 months and in the last year (date, location, reason) and concerns about falling.

3.9 Ethical considerations

Participants were informed about the objectives, procedures, implications and their rights. The contact of the responsible researcher was available for questions or doubts, at any time during the trial. Also, the same intervention was available for the control group after the end of the trial, due to ethical issues. Written information was offered with this information for analysis by the participants prior to consent (Appendix IV). Therefore, informed consent was provided by all participants at the enrolment phase, as seen in Appendix V.

Ethical approval for the ProBalance Project was granted by the Ethics Committee of the Health Service of the Autonomous Region of Madeira in January 2011 (Appendix VI).

3.10 Quality control

To ensure the quality of the execution, feasibility of the procedures and reliability of all measures were tested in the piloting phase of this research, through a pilot study.

The pilot study consisted in a "mini-RCT" that was performed between November and December 2011. The purposes of the pilot study were: (1) to estimate the test-retest reliability of the Fullerton Advanced Balance (FAB) scale (Rose, 2010); (2) to assess participant’s recruitment, adherence and retention in the ProBalance Program; and (3) to examine short-term changes in balance-related outcomes. This "mini-RCT" consists on a 4-week controlled trial, incorporating the pilot study of the ProBalance intervention designed to improve balance in older adults. This “mini-RCT” was prospectively registered in the Australian New Zealand Clinical Trials Registry Platform and the clinical trial registration number is ACTRN12611001164987 (for further details on the international registry, see http://apps.who.int/trialsearch/Trial.aspx?TrialID=ACTRN12611001164987).

The sample comprises 80 healthy community-dwelling men and women aged 65-80 years from Autonomous Region of Madeira (ARM), Portugal. In total, 6 eligible older adults were randomly allocated to the intervention group and other 6 to the waiting-list control group receiving usual care. The inclusion criteria of the pilot study were: (1) community-dwelling older adults aged 65-80 years; (2) to report at least one fall in the last year, or no falls, if FAB score was equal or lower than 30/40; and (3) to be able to walk independently. The exclusion criteria were: (1) the presence of cognitive impairment (assessed by the MMST); and (2) significant co-morbidities that would preclude participation (acute illness, progressive neurological disease, stroke, and unstable chronic conditions).

Informed consent was signed and the volunteers were received at the laboratory of the University of Madeira for assessments. A simple randomization process was used to allocate the participants to Intervention Group and Control Group using a coin toss. This procedure was done and recorded by an independent person, who was not a member of the research team. The time points for assessment were one week before starting the 4 week intervention, at 0 (pre-test), and 4 weeks (post-test), and all outcome and interfering variables were accessed at the three time points. Participants were assessed by one blinded and independent assessor. The protocol was fully completed, no adverse events (i.e. falls) or side effects were associated with the exercise intervention or the assessments, attrition rate was 0% and adherence to sessions was 100%.

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Chapter 4

Therapeutic exercise in Gerontological Rehabilitation: A literature analysis

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Bridge

This chapter comprises a theoretical article elaborated in the beginning of this research project. At the time, the research problem was not yet defined, and the review of literature addressed general clinical problems and theoretical issues. This article, entitled "Therapeutic exercise in Gerontological Rehabilitation: A literature analysis", targets a very broad topic, namely the associations between therapeutic exercise interventions and posture, gait and functional fitness in the older adults, as well as the role of rehabilitation nurses in this domain. However, important conclusions were drawn from this literature analysis, contributing for the understanding of the reasons that led a narrower research question in the present research process.

A version of this article, in the Portuguese language, was published in 2013 on an international scientific nursing journal, namely, *Referência* (Qualis B2).

This and other publications are described in the list of publications derived from this research (Appendix VII).

Abstract

With an aging population and an increasing demand of specific health care, from the standpoint of Rehabilitation Nursing, strategies to deal with potential determinants of the aging process that affect mobility should be based on current research results.

Therapeutic exercise, also known as kinesiotherapy, consists of a basic tool for the rehabilitation nurse specialist. However, few studies address the rationale and the applicability of such techniques in the context of gerontological rehabilitation.

This theoretical essay aimed to: (1) describe the associations between posture, gait and functional fitness in the older adults and therapeutic exercise interventions, and (2) identify references to the intervention of rehabilitation nurses in this domain.

We performed a review of literature with a reference search in all health journals included in the electronic database EBSCO HOST, published in the last 15 years. The analysis was qualitative, 168 articles were identified, of which 11 met the inclusion criteria.

The studies analyzed showed complementary results, describing benefits of therapeutic exercise on posture, gait and functional fitness in older adults. In the revised studies, special relevance is also given to balance as a related outcome. In balance, combined exercise was associated to significant improvements. There were no references to rehabilitation nurses' intervention.

Further research is needed to describe the specificity of therapeutic exercise in gerontological rehabilitation and the work of the rehabilitation nurse specialist in this field.

Key words: Rehabilitation Nursing, Aged, Mobility Limitation, Exercise.

Introduction

Recognizing the problematic that accompanies the demographic aging in Portugal and in the World, the dependence growth ratios (Statistics Portugal, 2009) and the increasing demands in health care, the gerontological rehabilitation is an area of growing interest.

Although therapeutic exercise, also known as kinesiotherapy, is recognized by specialist rehabilitation nurses as a basic feature in the clinical context, the lack of studies that address the rationale and the applicability of such techniques in the specific context of gerontological rehabilitation, determined the relevance of this research.

Thus, the clinical practice with older people as rehabilitation nurses, and specifically the need to validate an action plan focused on preventing limitations on mobility of older adults, led to the departure issues of this work: Which associations exist between the posture, gait and functional fitness of the older adults and therapeutic exercise? Are there publications discussing therapeutic exercise as an intervention used by the rehabilitation nurse specialist in the care of older adults?

In order to answer these questions, this article will have the following objectives: (1) to describe the relationships between posture, gait and functional fitness of older adults and therapeutic exercise interventions and (2) to identify references to the intervention of specialist nurses in this rehabilitation domain.

Intending to elaborate a theoretical article, we performed a literature review through a qualitative analysis of the type of articles published in refereed journals, an electronic survey was conducted using the database EBSCO HOST, selecting all databases in the area of health included in it. The publication period was set between January 1995 and January 2010 and the keywords used were: aging, older adults, aged, gerontological rehabilitation, nursing, posture, gait, physical fitness, mobility, therapeutic exercise, and exercise.

The research findings were vast, however, were excluded from this analysis and cataloging, all studies concerned other aspects, not biological or kinesiological of human aging, all literature reviews on the theme, all studies that studied only situations of specific pathology, as well as indexed without full-text articles available. Given these criteria, were identified by analyzing the title, 168 articles of these, were selected 11, presenting relevant references on the topic under study in the abstract, for a later full review.

It should be noted that in the abstract analysis , were considered for inclusion, studies that refer to exercise interventions with results in variables associated with posture, gait and functional fitness components, as well as, in studies that targeted older adults described as healthy or with functional disability. Of these, 11 were selected, presenting relevant references on the topic under study in the abstract, for a later full review. Since the term kinesiotherapy was not found as a descriptor in the studies or in the database, references to related terms were considered (gerontological rehabilitation, physical fitness, mobility, therapeutic exercise, and exercise), for inclusion in this literature review.

Literature Review

The changes caused by aging and therapeutic exercise

Given the aging population and the resulting demand for health care from the point of view of rehabilitation, it is important to meet and respond to the changes caused by aging as potential determinants of mobility limitations, as are the postural changes, gait and functional fitness in older adults, which we will address briefly. It is commonly seen in people with advanced age, neuromuscular limitations evidenced by muscle weakness, loss of muscle power and rapid muscle fatigue often associated with inactivity and the arising of chronic diseases, which aggravate the situation of limitation. However, the mechanisms underlying these muscle disorders are complex, being verified in addition to decreasing the transmission speed at the level of the neuromuscular junction, loss of muscle mass and muscle fiber (sarcopenia) and functional fitness and muscle fiber muscle and fat infiltration in skeletal muscle (Doherty, 2003). Regarding the rehabilitation intervention, the same author claims that the approaches recommended for the prevention and treatment of sarcopenia include increased physical activity at any age.

Regarding the bone component according to Germain-Lee, Checovich, Smith, and Lundin (2007), bone loss occurs with age, checking for a period of accelerated loss in postmenopausal women. Aging is responsible for decreased bone irrigation, decreased quantity and quality of osteoblasts, osteoclasts increased, decreased bone density and bone turnover, decreased calcium metabolism and reduction of the joint space, resulting in alteration of motion and functional changes.

Although the structure and bone remodeling depend on various factors such as mechanical stress, pharmacological agents and nutritional intake, Germain-Lee et al. (2007) emphasize the role of the mechanical load to increase indirectly bone mass, referring as an example the increase muscle mass. So, the role of therapeutic exercise in rehabilitation before the musculoskeletal aging is relevant.

The joint and ligament component also suffers the aging effects and is associated with changes in joint movement, such as walking, posture and functionality in older adults. In this field, the literature documents the increased ligament stiffness and decreased joint flexibility with impact on range of motion and posture. Studies have reported decreased joint range of motion of shoulder abduction, flexion and extension of the thigh, knee flexion, dorsiflexion and plantar flexion, extension and flexion of the cervical spine and flexion and extension of the lumbar spine (Amundsen, 2007).

The neuro-musculoskeletal changes associated with aging and compensatory positions, can cause postural changes of the axial skeleton (such as head tilt forward, the thoracic kyphosis, lumbar pain the rectified column, lumbar spine kyphosis, increased lumbar lordosis, scoliosis and slowdown of the basin) and of the appendicular skeleton (arising from the protraction of the scapula, contractures of the elbow, wrist and knee and slope changes of the hip, knee and ankle). These postural changes, besides associated with pain, determine dysfunction on gait or movement (Kauffman, 2007), affecting postural stability and balance, and causing frailty and risk of falling in older adults.

Pheasant and Schroeder (2007) reported that postural exercises, mobilization and muscle strengthening exercises are important preventive interventions in the rehabilitation of older adults.

The clinical importance of changes in posture and gait resulting from muscle-skeletal changes, determines interventions that include mobilization, stimulation, and strength, coordination, and balance exercises, among other therapeutic exercise interventions (Kauffman, 2007). According to Stott et al. (2006), a program of gerontological rehabilitation can have positive effects on the reduction of disability in older adults.

However, a gerokinesiological approach can also be the basis for a preventive therapeutic rehabilitation intervention. Namely, the use of kinesiotherapy, in promoting the movement (by using specific exercises) of muscle groups whose action is impaired by aging, could prevent and minimize musculoskeletal limitations, postures and movements associated with dysfunctional movements. Therefore, a specific functional assessment of older adults should be taken into account (Jones & Rose, 2005).

In the context of rehabilitation nursing, therapeutic exercise is also known as kinesiotherapy. Kinesiotherapy is described as the use of motion or exercise as therapy, based on knowledge of anatomy, physiology and biomechanics, and can be applied in the prevention, adaptation or complete rehabilitation of physical problems (Guimarães & Cruz, 2003).

Therefore, in the community setting, great impact is expected from therapeutic exercise in older adults, which we seek to describe through this analysis of the existing literature about the topic. Since this is a technical resource for the rehabilitation nurse specialist, and though there is a lack of literature addressing its relevance in gerontological rehabilitation nursing, it is important to attest its merits and applicability, as well as, the role of the rehabilitation nurse specialist in this domain.

Therapeutic exercise and posture, gait and functional fitness of older adults

A total of 11 studies addressed the associations between exercise interventions and posture, gait or the functional/physical fitness components of older adults. We considered a predominance of experimental studies (only three descriptive report associations observed between the study variables and variations of the movement, although they are not intervention studies) and a large variability in the methodologies used in the studies, particularly for the assessment of functional fitness. In this context and given the validity of the instruments and methodologies used in the studies, which are criterion for publication in scientific journals, and since the purpose of this review is not comparing studies, we considered the various outcomes alone and through qualitative analysis, we sought to identify complementarity between them.

Several experimental studies focused its intervention on physical fitness components in separate, confirming beneficial effects of the exercise, which we are going to address.

In the study developed by Carvalho et al. (2004), the generalized isokinetic exercise training was not significantly associated with increased muscle strength in older adults. However, the study done by Fahlman, Morgan, McNevin, Topp, and Boardley (2007) suggested that resistance training alone, or combined with aerobic training is effective in increasing strength and functional fitness in older adults, even when exercise is started with some functional limitations.

In another study done by Ribeiro et al. (2009), it was found that a fitness program instituted in a health center, there were improvements in overall functional fitness of older adults, especially in functional fitness, strength and coordination of the upper limbs. Studying this program period of detraining, yet, it was found an improvement in aerobic endurance.

Caromano, Ide, Kerbauy, and Streit (2009), in an experimental study in sedentary older adults studied the impact of a general exercise and walking program and found that both led to improvements in posture and gait, with better results for global exercises on posture and walk on the walking capacity. Verfaille, Nichols, Turkel, and Hovell (1997) found that resistance training can lead to gains in muscle strength and gait in older adults, being more effective when combined with balance training and step (gait), which were associated to significant improvements in balance and gait. In the same line, Protas and Tissier (2009) conducted a study in older adults with disability in identifying mobility and by applying a workout for muscle strength and walking velocity found improvements in functional fitness, strength and gait. Similarly, Marsh, Chmelo, Katula, Mihalko, and Rejeski (2009), studying the impact of two training programs in older adults with functional disability of lower limbs, concluded that gait training with a break to other exercises (tasks-oriented) had a more positive effect than the free gait training with the same distance covered.

Other studies have documented the association of physical activity in general (leisure time or not) in older adults, to increased quality of life (Mota Ribeiro, Carvalho, & Matos, 2006) and a greater capacity in mobility, particularly in the flat marsh and when climbing stairs (Malmberg, Miilunpalo, Pasanen, Vuori, & Oja, 2006), suggesting the importance of encouraging physical activity in older adults. Other revised longitudinal studies also show that the overall physical activity is associated with a smaller decline in functional fitness and lower mortality (Sihvonen, Rantanen & Heikkinen, 1998; Laukkanen, Kauppinen & Heikkinen, 1998).

Table 4.1 summarizes the reviewed studies on this topic, organized into two categories: (1) descriptive and correlational longitudinal studies, demonstrating associations between physical activity and functional fitness and survival in older adults; and (2) experimental studies, documenting the effects of various types of training that include motion (kinesiotherapy), on posture, gait, and functional fitness of older adults.

Table 4.1 Studies that address posture, gait, and functional fitness components.

Author / Year of Publication	Title of the study	Country	Type of Study	Objective	Methodology	Sample	Relevant conclusions
Malmberg et al. (2006)	Associations of leisure-time physical activity with mobility difficulties among middle-aged and older adults.	Finland	Descriptive and correlational longitudinal	Examine the amount and type of physical activity as a predictor of difficulty in walking and climbing stairs.	The subjects were evaluated in four moments: initially, 1, 10, and 16 years later, with a response rate of variation; Levels of physical activity and mobility were assessed through questionnaires.	The sample included 5259 subjects in 1980; 4602 in 1981; 4267 in 1990 and 1791 in 1996; Ages initially between 40 and 64 years.	Low levels of physical activity in leisure weekly Are associated with future risk of mobility difficulties in older men and women.
Laukkanen, Kauppinen & Heikkinen, (1998)	Physical activity as a predictor of health and disability in 75- and 80-years-old men and women: a five-year longitudinal study.	Finland	Descriptive and correlational longitudinal	Examine physical activity, as a predictor of health and functional fitness.	There were two moments of assessment through interviews and clinical examination of a group of older adults, with a time interval of 5 years (1989/90 and 1994/95); Physical activity was assessed by the questionnaire of Grimby (1986); The clinical evaluation used the ICD as a reference (WHO, 1987); NYHA (1964); scale of cancer evolution and functional capability scale of Steinbrocker (1942).	1st phase: The sample included 779 subjects, Aged between 75 and 80 years; 2nd phase: The sample included 660 subjects; Now with ages between 80 and 85 years.	Older adults with higher levels of physical activity compared with older adults to present a higher level of health and functional fitness.
Sihvonen, Rantanen, & Heikkinen (1998)	Physical activity and survival in older adults: a five year follow-up study	Finland	Descriptive and correlational longitudinal	Assess the association between physical activity levels and survival in older adults in a period of 5 years.	Data were collected through interviews in two moments: at the beginning of the study and 5 years after.	1st phase: The sample included 313 subjects with 75 years and 245 with 80 years. 2nd phase: 253 subjects aged 75 years and 172 subjects with 80	Higher levels of physical activity were associated to a greater survival.

Author / Year of Publication	Title of the study	Country	Type of Study	Objective	Methodology	Sample	Relevant conclusions
						years.	
Marsh et al. (2009)	Should physical activity programs be tailored when older adults have compromised function?	USA	Experimental	Determine the effectiveness of a walking program and other tasks in mobility verses a walking program only.	The subjects were divided into 2 groups; A training program (18 sessions to walk and tasks to a group and walk to another group) was applied; Mobility/physical fitness was evaluated by the Short Physical Performance Battery (SPPB).	The sample included 31 subjects; Average age of 76 years; Both sexes; Residents in the community.	Older adult patients submitted to walking program and other tasks showed an improvement of over and substantial in SPPB, when compared with the other group.
Protas & Tissier (2009)	Strength and speed training for elders with mobility disability	USA	Experimental	Assess the effect of a strength and gait training program in older adults with mobility limitation.	The training program was implemented for 12 weeks, 3 times per week; The parameters were evaluated by the time elapsed walking with specific monitoring tools (VO2 through facial mask and the portable analyzer) and by the Short Physical Performance Battery (SPPB).	The sample contained 11 subjects; Average age 77.2 years.	A strength and gait training program for 12 weeks resulted in a significant improvement in gait, strength and functionality in older adults with mobility limitation.
Caromano et al. (2009)	Comparative study of the effects of two programs of exercises - walking and general exercise - in posture and gait in healthy sedentary older adults	Brazil	Experimental	Compare the effects of two exercise programs (general exercises and walking) on posture and gait of healthy older adults.	The sample was divided into three groups: the experimental group 1 which general exercises were introduced; the experimental group 2, walk and a control group without applying activity; Body posture (Postural and height index) and gait (Gait Index) were assessed after 8 weeks.	The sample consisted of 30 subjects; Average age 68.7 years.	After 8 weeks of intervention, groups 1 and 2 showed an improvement Significant postural assessment, with better results for group 1. The two exercise groups obtained a significant improvement in gait index, while group 2 had the best results.

Author / Year of Publication	Title of the study	Country	Type of Study	Objective	Methodology	Sample	Relevant conclusions
Ribeiro et al. (2009)	Gym Program for the older adults at Health Center: assessment of functional fitness.	Brazil	Experimental	Analyze the influence of an exercise program for 24 weeks and a period of 8 weeks detraining on functional fitness of older adults from four Health Centers.	An exercise program, 3 times per week (24 days), followed by detraining (8 weeks) was applied to the sample; Functional fitness was assessed using the battery of tests AAHPERD.	The sample included 14 subjects; Average age 67.78 years; females.	The program contributed to improving overall functional fitness of older adult women. The upper limb strength and coordination achieved major changes. In the period of detraining program, an improvement in aerobic endurance was noted.
Fahlman et al. (2007)	Combination training and resistance training as effective interventions to improve functioning in elders	USA	Experimental	Determine whether resistance training or a combination of resistance and aerobic training improves functional fitness in older adults with limitations.	The sample was divided into three groups: the experimental group 1 was applied to resistance training; the experimental group 2, combination of resistance and aerobic training; The control group had no intervention; An assessment of strength and functional fitness (6 tests) was performed before and 17 weeks after training.	The sample included 109 subjects; 74.6 Middle Ages; 75.8 and 76.5 years, respectively, for the 3 groups.	The resistance, endurance and aerobic training were able to significantly increase strength, endurance and functional fitness of older adults with limitations.
Mota et al. (2006)	Physical activity and health related quality of life in older adult participants and non-participants in regular physical activity programs	Portugal	Experimental	Compare the quality of life among participants in formal programs of physical activity and non-participants, and to determine	The sample was divided into two groups: Control group (n = 42) not included in the exercise program and an experimental (n = 46) group, which was involved in a physical activity program;	The sample included 88 subjects; Age greater than 65 years.	Active older adults had a higher quality of life than older adults who did not participate in a physical activity program.

Author / Year of Publication	Title of the study	Country	Type of Study	Objective	Methodology	Sample	Relevant conclusions
				factors that may predict such participation.	Assessment of quality of life was performed by questionnaire SF 36.		
Carvalho et al. (2004)	Muscle strength in older adults I - will be widespread enough intense training to promote increased muscle strength in older adults of both sexes?	Portugal	Experimental	Determine the effect of a general program of physical activity, with a duration of 6 months, the maximum isokinetic strength of the knee extensors and flexors in older men and women.	The sample was submitted for 6 months to a bi-weekly program of general physical activity; The maximum isokinetic strength of the knee extensors and flexors was assessed using an isokinetic dynamometer (Biodex System 2, USA) in two different speeds (60 and 180 sec.) before and after the training program.	The sample included 26 subjects; Average age 68.1 for men (7) and 69.5 in women (18).	The results showed there were no significant changes in muscle strength in older adults after general training.
Verfaille et al. (1997)	Effects of resistance, balance, and gait training on reduction of risk factors leading to fall in elders.	USA	Experimental	Compare the effects of resistance training alone or combined resistance training, balance and step (gait) in balance and gait of older adults.	The sample was divided into two groups: the experimental group to which was applied the combined training and the control group, with resistance training and relaxation; 12-week intervention was implemented; Assessments of strength (maximum voluntary contraction), gait (gait velocity and step length), static balance (Romberg signal), and dynamic balance (tandem walk) were performed prior and after the intervention.	The sample included 39 subjects; Ages between 65 and 83 years.	Both groups showed increased strength and gait velocity; Only in the combined training significant improvements in balance and gait were observed.

The different typology of studies enabled us to take different conclusions. Particularly in descriptive studies, we obtained indicators of relations between functional fitness and physical activity or general movement. On the other hand, the set of revised experimental studies emphasized the effect of various types of therapeutic exercise interventions, on posture, gait and functional fitness of older adults.

Referring to interventions that impact on posture and gait, the reviewed studies make reference to single and multiple exercise type intervention with positive impact on these variables. The studies reviewed showed that aerobic and resistance training had a positive effect on strength and functional fitness of older adults (Fahlman et al., 2007), and also balance and gait, particularly when associated with balance and gait training (Verfaille et al. 1997). Muscle strength and walking velocity training were associated with improvements in functional fitness, strength and gait (Protas & Tissier, 2009). General exercise training and walking, as well as general physical activity, were associated with a generalized increase in muscle strength and improved posture and gait (Caromano et al, 2009; Carvalho et al, 2004). Also, general physical activity was associated with a greater mobility capacity (Malmberg et al. 2006), and improved quality of life (Mota et al., 2006), inferior functional fitness decline (Laukkanen, Kauppinen & Heikkinen, 1998) and better survival rates (Sihvonen, Rantanen & Heikkinen, 1998). As result, these findings allow us to identify also other variables associated with this subject, which have not been analyzed in the present research.

Despite the complementary results of the various studies, consideration should be given to the studied populations. The studies were conducted in different countries of Europe, America and Australia, which determines the possibility of detachment of the context-related variables, which is not analyzed in this work. An example is the different opportunities to exercise and the availability of rehabilitation services.

The results of this study, that examined the existing scientific evidence on the relationship between posture, gait and functional fitness of older adults and therapeutic exercise interventions, confirm the beneficial effects of the kinesiotherapy interventions previously described (Jones & Rose, 2005; Stott et al., 2006).

The professionals involved in the practice of therapeutic exercise

The referenced studies lead us to see that the research has been growing within the gerontological rehabilitation in recent years. It has been found that most of the analyzed studies were published in the last five years. However, we found that this approach is taken from different areas of study and different professionals involved in the rehabilitation of older adults, particularly in the area of physical education, sports and physical therapy, while the expression of rehabilitation nurses seldom mentioned in this context.

When we tried to document the specialist rehabilitation nurse intervention, it was found that this was not studied or cited in any studies identified in this review, glimpsing the low profile of this professional in the existing publications on this topic.

However, specializations in rehabilitation nursing do not exist, are relatively recent or are not certified in many countries worldwide. Unlike what happens in Portugal, the universe of these professionals in the world could be limited in relation to others in the field of rehabilitation, determining a smaller number of scientific publications in journals indexed in the searched database.

In most of the studies, the need for development of further research in this area is stated, which is reinforced by the results of this analysis of the literature.

This analysis of the literature allowed us to identify the positive impact of various exercise interventions, as well as other important variables that could be addressed in further research on this topic. In the revised studies, special relevance was given to balance. Balance and balance-related outcomes (as strength and gait), have shown to be an important focus of this type of research, due to its importance in the functionality of older adults. Further analysis of this topic should target these variables.

Therapeutic exercise is associated to benefits in posture, gait, and the components of functional fitness, as well as balance, in older adults, with resulting effects on global mobility, quality of life and also survival. The reviewed studies are limited and partially addressed the subject of this review; however, we observed coherence and complementarity in the findings.

Through the analysis of existing scientific evidence on the subject of the present review, the results of this study confirm the applicability and relevance of therapeutic exercise interventions in the context of gerontological rehabilitation.

It is important to undertake the limitations of this study. First, this study comprises a review of literature and qualitative analysis of the results; however, the generalizability of the results is compromised. The option for another design (a systematic review of literature or a meta-analysis) would be necessary to overcome this limitation. Second, the availability of full-text retrieval as inclusion criteria and the inability to analyze quantitatively the cause-effect relationships identified due to the different methodologies used in the reviewed studies. Lastly, the vast scope of the subject may have limited the depth of the study, however, allowing an overview of the beneficial effects of therapeutic exercise.

The contribution of various disciplines is an asset in gerontological rehabilitation, suggesting that a multidisciplinary intervention could be advantageous in the clinical setting. In addition, the existent published scientific literature, does not address therapeutic exercise (kinesiotherapy) in older adults held by rehabilitation nurses. As a practical implication of these findings, we believe that the identification of this gap in literature can be an incentive for rehabilitation nurses, towards the production of scientific research that demonstrates health gains from exercise interventions, which we consider a mainstay of clinical practice in the field of gerontological rehabilitation nursing.

Conclusion

Therapeutic exercise, also known as kinesiotherapy, is a technical resource for the rehabilitation nurse specialist in gerontological rehabilitation. Therefore, it is important attest its fundament and applicability.

This analysis of the literature allowed us to describe the beneficial effect of various therapeutic exercise interventions, in posture, gait and functional fitness of older adults, as well as balance, justifying its relevance in gerontological rehabilitation.

The results of 11 studies that examined the relationship between posture, gait and functional fitness of older adults and exercise interventions, reinforce the importance of this type of intervention in the context of gerontological nursing rehabilitation.

Seeking to meet the second objective of this study, namely to identify references to the intervention of a rehabilitation nurse specialist in this field, the reviewed studies show the absence of references to these professionals. We believe that the published scientific literature reviewed in this article, does not show the scope of the therapeutic exercise interventions held by rehabilitation nurses, particularly in Portugal, where they are recognized and certified professionals.

More studies are needed to define the specificity of therapeutic exercise in gerontological rehabilitation nursing, and assess the effect of specific intervention plans in gerontological rehabilitation nursing that can be applied and reproduced in the clinical context.

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Chapter 5

The ProBalance Program for improving balance in older adults: A pilot study

Bridge

This chapter comprehends an article reporting the first research study developed in the context of the ProBalance project. This article is entitled *"The ProBalance Program for improving balance in older adults: A pilot study"*. This study is a pilot randomized controlled trial focused on the feasibility of the ProBalance program. Results address the reliability of all assessments, and recruitment, adherence and retention rates, as well as, a preliminary analysis of short-term changes in balance-related outcomes.

This article is under review by co-authors for submission to the *Archives of Physical Medicine and Rehabilitation*.

Abstract

Exercise seems to be moderately effective in improving clinical balance outcomes. This study investigates the feasibility of the ProBalance program - *Prehabilitation and Rehabilitation Nursing: balance/fall risk in a community-dwelling older adults*, in terms of reliability of assessments, recruitment, adherence and retention rates. A specific aim is to examine short-term changes in balance-related outcomes.

A total of 80 community-dwelling older adults, aged 65-80 years, were assessed for eligibility. Twelve women (mean age of 72.8±3.4 years) were randomized into the ProBalance intervention group (IG) (n = 6) and into a non-intervention wait-list control group (CG) (n = 6). The IG undertook 12 training sessions of 60 minute each, three times per week, during four weeks. Pre- and post-test assessments included balance, gait parameters, functional fitness, health-related quality of life (HRQL), cognition, falls, and physical activity.

The study protocol and intervention were fully applied and a high adherence and retention was verified (100%). Intraclass correlation coefficient (R) for the total Fullerton Advanced Balance scale score was 0.885. In gait parameters, R ranged between 0.717 (velocity) and 0.799 (stability ratio). For functional fitness, R was between 0.689 (arm curl) and 0.987 (back scratch). High R values were also found for HRQL- physical (0.984) and mental (0.930), cognition (0.789), falls efficacy (0.940), and habitual physical activity (0.978). Only in the IG, there was a statistically significant increase in total FAB scale score ($p = 0.007$), arm curl ($p = 0.041$), and HRQL- physical ($p = 0.019$) and mental ($p = 0.013$) from baseline to post-intervention. In the CG, significant changes were seen in cadence ($p = 0.024$) and chair-sit-and-reach test ($p = 0.029$). No statistically significant differences were observed in the remaining variables, in both, IG or CG.

This study demonstrates that the ProBalance program is feasible (in terms of reliability of assessments, recruitment, adherence and retention) and has a promising effect on balance scores of older adults. A larger sample and a longer intervention period are needed in order to test the program’s efficacy.

Key words: Rehabilitation nursing, ProBalance Program, Reliability, Balance, Community-dwelling, Older adults.

Introduction

Falls in older adults living in the community and its impact on individual and public health is a major concern for the health care and for the society (WHO, 2007).

Previous studies have shown that falls are the most frequent accident and the leading cause of fatal injury in older adults. In the European Union, 53% of the total injury deaths and 82% of fatal fall injuries, happened in people 60 years and older. In this age group, falls accounted for 28% of all causes of injury-related deaths (EuroSafe, 2013). In Portugal, 15% of domestic and leisure accidents happened in the older adults (65 and older) and falls accounted for 87.1% of all accidents in older adults aged 65-74 years (NHORJ, 2011). In the Autonomous Region of Madeira (ARM), Portugal, Gouveia (2011) reported that 36% of a sample of community dwelling older adults had, at least, one fall in the past year. This is in line with worldwide studies showing that at least, 30% of community-dwelling older adults (aged 65 and older) experienced one or more falls each year and that 10 to 15% of these falls were associated with serious injuries (American Geriatrics Society, British Geriatrics Society, & American Academy of Orthopaedic Surgeons Panel on Falls Prevention, 2001; Gillespie et al., 2012; Rubenstein, 2006; Sturnieks, George, & Lord, 2008).

Falls seem to be multifactorial in their origin. Chronic conditions, balance and gait impairments, functional disabilities, general physical inactivity, vision problems, cardiovascular factors, and medications are predisposing factors for falls, while home hazards, footwear, and multifocal or new glasses are precipitating factors (Tinetti & Kumar, 2010). It was also shown that balance declines with aging (Rose, 2010) and that poor balance is associated with an increased risk of falling (Howe, Rochester, Neil, Skelton, & Ballinger, 2011). There is scientific evidence that some types of exercise are moderately effective in improving clinical balance outcomes and reducing falls in older adults (Balzer, Bremer, Schramm, Lühmann, & Raspe, 2009; Costello, & Edelstein, 2008; Gillespie et al., 2012; Sherrington et al., 2008; Howe et al. 2011). Finally, there is evidence that some types of exercise including gait, balance, co-ordination and functional tasks, strengthening exercise, 3D exercise and multiple exercise types are moderately effective in improving clinical balance (Howe et al., 2011).

In this context, high methodological quality research using core outcome measures and adequate surveillance is necessary to accomplish more robust evidence on this topic. According to Portney and Watkins (2009), reliability represents the extent to which a measurement is consistent and free from error. This study investigates the feasibility of the ProBalance Program - *Prehabilitation and Rehabilitation Nursing: Balance/fall risk in community-dwelling older adults*. At the most specific level, the purposes of the present study were: (1) to estimate the test-retest reliability for all measures including balance; (2)

to assess participant's recruitment, adherence and retention in the ProBalance program; and (3) to examine short-term changes in balance-related outcomes. Reliabilities of functional fitness, health-related quality of life (HRQL), cognition and physical activity were also studied. Results from this study will assist health professionals in optimizing procedures and estimating recruitment, retention and sample size in a larger scale randomized controlled trial (RCT).

Method

Design, sample and participants

This "mini-RCT" consists in a pilot study for the development of a larger scale RCT. Briefly, it consists on a 4-week RCT, incorporating a pilot study of a ProBalance program intervention in order to improve balance in older adults. This "mini-RCT" was prospectively registered in the Australian New Zealand Clinical Trials Registry Platform and the clinical trial registration number is ACTRN12611001164987.

The sample comprises 80 healthy community-dwelling men and women aged 65-80 years from Autonomous Region of Madeira (ARM), Portugal. In total, six eligible older adults were randomly allocated to the intervention group (IG) and other six to the waiting-list control group (CG) receiving usual care. The inclusion criteria were: (1) community-dwelling older adults aged 65-80 years; (2) to report at least one fall in the last year, or no falls, if Fullerton Advance Balance (FAB) scale score was equal or lower than 30/40; and (3) to be able to walk independently. The exclusion criteria were: (1) the presence of cognitive impairment (assessed by the Metropolitan Medical Strike Team [MMST]); and (2) significant co-morbidities that would preclude participation (acute illness, progressive neurological disease, stroke, and unstable chronic conditions).

Participants were recruited through advertising in a regional newspaper, posters, flyers and social networks, as well as through presentations by the main researcher in religious communities and social institutions. Advertisement started in September 2011 and was completed in October 2011; recruitment happened in November 2011. The intervention was performed between November and December 2011, during four consecutive weeks.

Informed consent was signed and the volunteers were received at the laboratory of the University of Madeira for assessments. After screened for eligibility, baseline assessments were done to eligible participants. A simple randomization process was used to allocate the participants to IG or CG using a coin toss. This procedure was done and recorded by an independent person, who was not a member of the research team.

All eligible participants (n=12) took part in the test-retest reliability study. Each participant was assessed twice with one week of interval. The same research members took the measurements on the two occasions and under similar conditions. Participants were assessed by blinded and independent assessors. The research team included six Registered Nurses and an expert in the field of gerokinesiology, who coordinated the assessments and gave specific training prior to the trial (12 hours).

Intervention

Following the preliminary evaluation, the IG received a multidimensional rehabilitation nursing intervention – the ProBalance program. This exercise intervention included a multiple risk approach, namely, an exercise program tailored for older adults with moderate risk for falling. The ProBalance is a theory-driven program, which adopts a multidimensional approach to balance and mobility in independent-living older adults with balance impairments. It targets important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness (Rose, 2011).

Rehabilitation sessions were administered by only one trained rehabilitation nurse, during 4 weeks, 3 days per week, 60-min duration/session. The intervention included: (1) multisensory training (approaching visual, somatosensory and vestibular systems); (2) center of gravity control training; (3) proactive and reactive postural strategy training; (4) gait pattern enhancement and variation training; and (5) strengthening and flexibility training. The rationale for the development of this type of intervention has been described elsewhere (Rose, 2010). The remaining members of the research team assisted in the exercise preparation and kept the security of participants in a ratio of 1:1. Aiming to enhance the adherence of the participants, one additional training session was given in the beginning of the intervention, with 45-min duration. This educational component addressed general aspects of fall prevention. The CG did not attend any rehabilitation session during the intervention. For ethical reasons, sessions were available to the CG at the end of the trial.

Outcomes

Balance

Balance was assessed through the FAB scale (Rose, Lucchese, & Wiersma, 2006). The FAB scale includes a combination of static and dynamic balance activities performed in different sensory environments. The scale comprises 10 items, namely: standing with feet together and eyes closed; reaching forward to retrieve an object (pencil) held at shoulder height with outstretched arm; turning 360 degrees in right and left direction in a circle; stepping up and over a 15 cm bench; tandem walking; standing on one leg; standing on foam with eyes closed; jumping for distance; walking with head turns; and recovering from an unexpected loss of balance. Each item is scored on an ordinal scale ranging from 0 to 4 points; the maximum score for the FAB scale is 40 points. The change scores were also analyzed. Changes in the fall risk were calculated taking into account that 1-point change in total FAB scale score is associated to a 8% change in fall risk, according to Hernandez and Rose (2008).

Gait parameters

Participants walked a distance of 50 feet (15 m) at preferred and maximal speeds. The distance between 10 and 40 feet (3 and 12 m, respectively) was timed to calculate velocity (m/sec) and other gait measures. The number of steps taken over the 9 m distance was counted by visual observation in order to calculate cadence (steps/sec) and stride length (m/stride) (Rose 2010). The gait stability ratio was calculated from cadence (steps/s) and velocity (m/s), and expressed in steps/m (Cromwell & Newton, 2004). A detailed description of the the 30-foot (9 m) walk test was reported by Rose (2010).

Functional fitness

Functional fitness was assessed with the Senior Fitness Test (SFT) developed by Rikli and Jones (1999a, 1999b). This six-item test battery includes chair stand test (lower body strength), arm curl test (upper body strength), chair sit and reach test (lower body flexibility), back scratch test (upper body flexibility), 8-foot up-and-go test (agility/dynamic balance) and 6-minute walk test (aerobic endurance). All participants received the same instructions about the procedures of each test and performed one or two trials to become familiarized with the task. A detailed description of the evaluation procedures, namely, equipment, procedure, scoring and safety precautions can be found in the SFT manual (Rikli & Jones, 2001).

Health-related quality of life

The Medical Outcomes Survey Short Form-36 (MOS SF-36) questionnaire was applied to assess HRQL (Ware & Sherbourne, 1992). The MOS SF-36 is a widely used, reliable, and a valid criterion measure of HRQL in Portuguese population (Ribeiro, 2005). The MOS SF-36 questionnaire has 36 questions that measures eight domains of HRQL. Physical functioning component comprises limitations due to physical health (role-physical), bodily pain, and general health. Mental component includes limitations due to emotional health (role-emotional) and mental health. Each domain is scored using a scale ranging between 0 and 100, with higher scores indicating a higher HRQL.

Cognition

The Mini-Mental State Test (MMST) (Folstein, Folstein & McHugh, 1975) was used to assess the mental state. The MMST is a widely used, reliable, and valid criterion measure of mental health that provides information on different cognitive parameters, containing questions grouped into seven categories, each designed to evaluate cognitive "functions" as a specific orientation to time (5 points), spatial orientation (5 points), registration of three words (3 points), attention and calculation (5 points), recall of three words (3 points), language (8 points) and visual constructive ability (1 point). The MMS scores range from 0 (high degree of cognitive impairment) to 30 points, which corresponds to a better cognitive ability. The MMS questionnaire was validated for the Portuguese population by Gerreiro et al. (1994). The cut-off points used to detect cognitive impairment were: ≤ 15 points (no education), ≤ 22 points (1-11 years of education) and ≤ 27 points (higher than 11 years of education).

Falls efficacy

The Falls Efficacy Scale (FES) (Tinneti, Richman, & Powell, 1990) was used to measure the fear of falling. The FES is a reliable and valid tool to assess the fear of falling in Portuguese population (Melo, 2011). FES assesses an individual's perceived confidence at the completion of 10 relevant and common tasks of everyday life, such as: (1) dressing and undressing; (2) prepare a light meal; (3) taking a bath or shower; (4) sitting/lift chair; (5) lying/get out of bed; (6) answer the door or the phone; (7) walking into the house; (8) reach for shelves; (9) light housework; and (10) small purchases. The confidence that older adults have to carry out the activities without falling, is represented in a 10-point scale ranging from "no confidence" (10 points) to "completely confident" (1 point). The total score of the FES is the sum of the scores obtained in each of the 10 items. The minimum score is 10 and the maximum is 100; the lower is the score, the lower the trust, translating into low self-efficacy.

Habitual physical activity

Habitual physical activity was assessed using the modified Baecke questionnaire (Voorrips, Ravelli, Donelmans, Deurenberg & Staveren, 1991). Participants reported physical activities during the last year. This questionnaire includes three specific domains: household activities, sport activities, and other physical activities in leisure time. Recently, this questionnaire was validated in Portuguese older adults by Azevedo (2009) using accelerometers as a criterion.

Statistical analysis

Data were entered twice into the computer by two different people (each person entered the data once, in a total of two entries) and were cross-referenced in a specific software to detect input errors. Exploratory analysis of the data took place through the usual procedures for identifying outliers and normality of the distributions. Intraclass correlation coefficient (R) was used to assess test-retest reliability. Paired student t-tests were used to assess the difference between means in the beginning and terminus of the intervention study. All analysis were performed in the Statistical Package for Social Sciences (SPSS), version 20. The level of significance was set at $p<0.05$.

Results

A total of 80 potentially eligible participants attended to the Probalance program. From the 68 excluded participants, 55 did not meeting inclusion criteria, seven declined to participate and six were not interested in participating or presented other reasons. Participants in the RCT consisted of 12 women with a mean age of 72.8±3.4 years who were randomized and allocated either to the IG (n=6) or the CG (n=6), and followed up for four weeks. Figure 5.1 shows the participants flow in the pilot study.

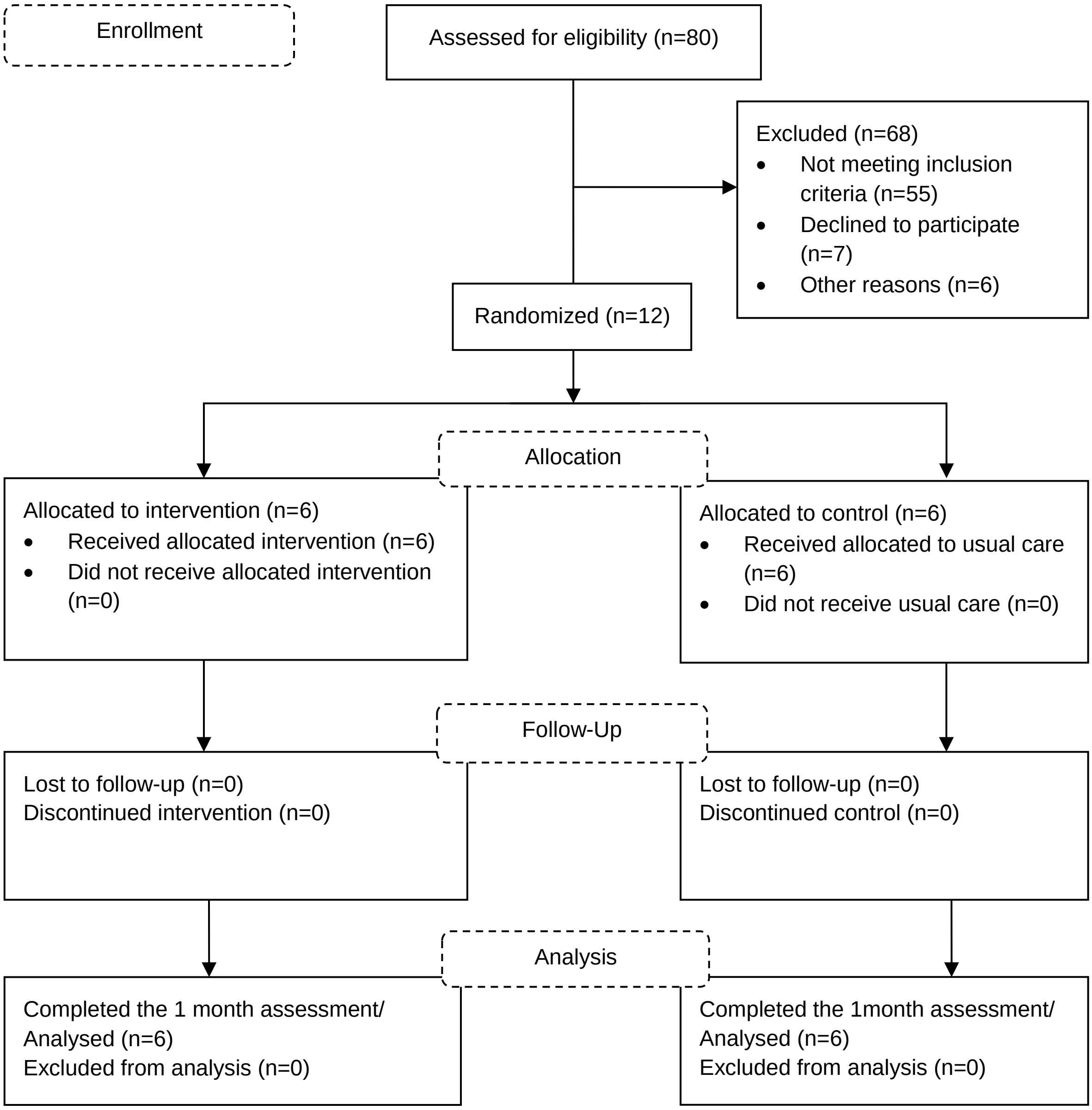

Figure 5.1 Participant flow of the pilot study.

Means, standard deviations, R, and 95% confidence intervals for balance, gait parameters, functional fitness, HRQL, cognition, falls efficacy, and habitual physical activity are presented in Table 5.1. R value for total FAB scale is 0.885, indicating a good level of reliability. In gait parameters, R ranges between 0.717 (velocity) and 0.799 (stability ratio). For functional fitness R range between 0.689 (arm curl) and 0.987 (back scratch). High R values are also found for HRQL- physical (0.984) and HRQL-mental (0.930) components. R values for cognition, falls efficacy, and habitual physical activity were 0.879, 0.940, and 0.978, respectively.

Table 5.1 Test-retest reliability for balance, gait parameters, functional fitness, health-related quality of life, cognition, falls efficacy, and habitual physical activity: pilot study (n = 12).

Variables	Test M (sd)	Retest M (sd)	R	95% CI
Balance				
Total FAB (score)	28.25 (2.01)	28.58 (2.39)	0.885	0.611-0.967
Gait				
Velocity (m/sec)†	1.57 (0.20)	1.67 (0.26)	0.717	0.112-0.916
Stride length (m/stride)†	1.40 (0.13)	1.48 (0.14)	0.795	0.095-0.946
Cadence (Steps/sec) †	2.25 (0.18)	2.26 (0.27)	0.724	-0.015-0.922
Stability ratio (steps/m)†	1.44 (0.14)	1.36 (0.13)	0.799	0.133-0.946
Functional fitness				
Chair stand test (n)	14.92 (2.64)	16.17 (2.08)	0.827	0.251-0.953
Arm curl test (n)	16.67 (3.14)	16.58 (2.75)	0.689	-0.158-0.912
Chair sit-and-reach test (cm)	2.96 (9.44)	2.58 (9.39)	0.923	0.732-0.978
Back Scratch test (cm)	-15.53 (9.28)	-15.21 (9.82)	0.987	0.957-0.996
8-foot up-and-go test (s)	6.05 (0.78)	5.88 (0.80)	0.908	0.698-0.973
6-minute walk test (m)	461.42 (1.88)	487.73 (42.80)	0.813	0.319-0.949
Health-related quality of life				
Sf-36 physical component (score)	28.25 (2.01)	198.98 (51.89)	0.984	0.945-0.995
Sf-36 mental component (score)	1.57 (0.20)	254.06 (71.43)	0.930	0.753-0.980
Cognition				
Mini mental state test (score)	26.50 (2.65)	26.58 (2.27)	0.879	0.569-0.965
Fall efficacy scale (score)	89.92 (7.97)	91.25 (8.53)	0.940	0.801-0.982
Habitual physical activity (total; score)	5.31 (2.92)	5.25 (2.88)	0.978	0.924-0.994

M (sd), mean ± standard deviation; R, intraclass correlation coefficient; FAB, Fullerton Advanced Balance; CI, confidence interval.†walk a distance of 15 meters at a maximal speed.

Main results for balance, gait parameters, functional fitness, HRQL, cognition, falls efficacy, and habitual physical activity at baseline and post-intervention are shown in Table 2. Only for the IG, there was a statistically significant increase in total FAB scale score from pre-test (M=27.83, SD = 1.83) to post-test (M=31.67, SD =2.42), t (5)= -4.39, p=0.007. Similar changes for the IG were seen for arm curl (functional fitness) [pre-test (M=15.83, SD = 2.64) to post-test (M=18.00, SD =2.10), t (5) = -2.74, p=0.041], HRQL – physical component [pre-test (M=171.28, SD =22.80) to post-test (M=232.37, SD =41.11), t (5)= -3.40, p=0.019], and HRQL – mental component [pre-test (M=217.36, SD = 65.34) to post-test (M=303.42, SD =33.86), t (5)= -3.735, p=0.013]. In the CG significant changes were seen in cadence (*p* = 0.024) and chair-sit-and-reach test (*p* = 0.029). In addition, no statistically significant differences were seen in all other gait parameters nor in the remaining functional fitness test in both groups (see table 5.2).

Table 5.2 Main results for balance, gait parameters, functional fitness, HRQL, cognition, falls efficacy and habitual physical activity at baseline and post-intervention by group: control and intervention.

	CG (n = 6)				IG (n = 6)			
Variables	Pre-test‡	Post-test‡	Δ score	p	Pre-test‡	Post-test‡	Δ score	p
Balance								
Total FAB (score)	29.33±2.80	29.50±2.81	0.17	0.695	27.83±1.83	31.67±2.42	3.83	0.007
Gait								
Velocity (m/sec)†	1.60±0.13	1.67±0.11	0.07	0.158	1.74±0.34	1.68±0.34	-0.06	0.521
Stride length (m/stride) †	1.47±0.15	1.45±0.15	-0.02	0.363	1.49±0.14	1.53±0.14	0.04	0.181
Cadence (Steps/sec) †	2.19±0.20	2.32±0.23	0.13	0.024	2.33±0.33	2.19±0.36	-0.14	0.366
Stability ratio (steps/m)†	1.37±0.15	1.39±0.14	0.02	0.363	1.35±0.13	1.32±0.13	-0.04	0.175
Functional fitness								
Chair stand test (n)	17.67±1.03	16.67±1.97	-1.00	0.203	14.67±1.75	16.00±1.79	1.33	0.062
Arm curl test (n)	17.33±2.88	16.33±1.51	-1.00	0.229	15.83±2.64	18.00±2.10	2.17	0.041
Chair sit-and-reach test (cm)	7.25±6.80	9.75±7.87	2.50	0.029	-2.08±9.78	3.67±4.49	5.75	0.091
Back Scratch test (cm)	-14.58±7.70	-16.42±6.22	-1.83	0.056	-15.83±12.33	-18.00±13.59	-2.17	0.068
8-foot up-and-go test (s)	5.64±0.55	5.85±0.83	0.21	0.279	6.11±1.00	5.85±0.78	-0.26	0.075
6-minute walk test (m)	477±56.48	466±62.69	-11.50	0.739	501±14.52	484±31.93	-16.43	0.186
Health-related quality of life								
Sf-36 physical component (score)	226.69±59.69	229.04±46.11	2.35	0.938	171.28±22.80	232.37±41.11	61.09	0.019
Sf-36 mental component (score)	290.75±61.03	268.33±75.83	-22.42	0.263	217.36±65.34	303.42±33.86	86.06	0.013
Cognition								
Mini mental state test (score)	26.17±2.79	26.67±3.14	0.50	0.681	27.00±1.79	27.00±3.41	-0.00	1.000
Fall efficacy scale (score)	91.83±6.68	89.17±11.89	-2.67	0.451	90.67±10.71	91.00±7.59	0.33	0.957
Habitual physical activity (total; score))	6.25±3.78	5.86±3.18	-0.39	0.541	4.25±1.27	5.58±2.82	1.33	0.872

†Walk a distance of 15 meters at a maximal speed; ‡values are means and standard deviations; CG, control group; IG, intervention group; Δ score, change between pre- and post-test

Discussion

This work incorporates a pilot study of a larger scale RCT aiming to assess the effect of a gerontological rehabilitation nursing program in a group of community-dwelling older adults living in ARM, Portugal. The main outcome of this study was balance.

One of the most important requirements of any assessment is reliability (Portney & Watkins, 2009). In the current study, the test-retest reliability for all measurements was between 0.689 and 1.000, indicating moderate to good levels of reliability (Safrit, 1990). The feasibility of ProBalance program in a 4-week RCT, involving 12 participants, was verified since the protocols and intervention were fully applied. Furthermore, high adherence and retention rates were seen in the pilot study, since all participants completed the two assessments and the intervention program or control. The efficacy of this pilot study was expressed by the change scores of the main balance outcome for the IG. For the total FAB scale scores, the IG showed a change score of 3.83 points, which represents a 40% decrease in fall risk, considering that a 1-point change in total FAB scale score is associated to an 8% change in fall risk (Hernandez & Rose, 2008).

The intraclass correlation coefficient for balance was 0.885 in this study. This value is somewhat lower than that report by Rose, Lucchese, and Wiersma (2006) using a North-American sample of 31 community dwelling older adults ($R = 0.96$). All functional fitness tests have also shown moderate-to-high reliabilities ($0.689 \leq R \leq 0.987$). Except for arm curl test (that in our study we had the lowest reliability, $R=0.689$), in the remaining tests we found similar reliabilities than those report by Gouveia et al., (2013), ranged from 0.75 to 0.90 in 802 participants (401 men and 401 women) living ARM, Portugal. However, Rikli and Jones (1999a) reported test-retest reliabilities for SFT items higher than ours, ranged from 0.80 to 0.98. In the gait parameters we found lower but acceptable reliabilities, R ranged from 0.717 to 0.795, according to the cutoff point of 0.70 suggested by Safrit (1990).

The second purpose of this study was to assess recruitment, adherence and retention in ProBalance program. The recruitment demanded an on-site screening to all volunteers. The eligibility rates among participants on this preliminary screening (15%) was lower than in a previous study by Ory et al., (2002). On the basis of the rigorous eligibility criteria and targeted sampling in our study, eligibility rates were low. Therefore, changes in the eligibility criteria could be a solution to increase the eligibility rate in main RCT. In regard to the retention in the program, all participants in this study completed the assessments and intervention program, and the protocol was fully applied. No adverse events related to the study were reported. However, an obstacle to participation was identified, specifically, the fact that the location of the study’s laboratory was not easily accessible by public transportation. Recommendations to reduce the frequency of intervention can be considered in order to maintain adherence in longer periods of intervention.

The third purpose of this pilot study was to examine short-term changes in balance-related outcomes. The efficacy of multidimensional interventions using multiple exercise types, for improving balance in older people has been previous reported by Howe et al. (2011). In general, the more effective programmes involved dynamic exercise in standing and ran for 12 weeks, three times per week. Another study by Westlake and Culham (2007) found improvements in the total FAB scale score after an 8-week exercise intervention. These results are in line with the current study, although our program consisted in 4-week intervention, 3 sessions per week, in a total of 12 hours of training. Notwithstanding, other pilot RCTs, with shorter periods of intervention also showed similar results (Kaesler et al., 2007; Nitz, Kuys, Isles, & Fu, 2010; Bateni, 2012; Kathleen, & Dold, 2013). In the current study, the use of the FAB scale and the type of intervention could explain the statistical increase in balance. As referred before, the ProBalance intervention is a theory-driven program, adopting a multidimensional approach to balance and mobility in independent-living older adults with balance impairments (Rose, 2010). In addition, we used the FAB scale that is a valid and reliable assessment tool (Rose, et al., 2006) for consider multi dimensions of balance.

Our data showed a short-term increase in HRQL. There is accumulated evidence showing an association between participating in physical activity programs and physical and psychological well-being, with the reduction of depression and anxiety, and the increase of self-esteem and positive affect (Spirduso, Francis, & MacRae, 2005; McAuley et al. 2006, Fortuño-Godes et al. 2013). Again, we did not expect any short-term changes in HRQL dimensions in our pilot study. Probably, the main explanation for these results was the fact that the concept of quality of life is very broad and dynamic, with an emphasis on the subjective dimension (WHO, 1993). In general, the absence of any statistical significant difference between baseline and follow-up measurements in gait parameters and the majority of the functional fitness tests could be explained by the short duration of the training program. The significant changes seen in cadence and chair-sit-and-reach test for the intervention group could be explained by an increased awareness and motivation in the assessments, however, further research is needed to further analyze this relation and potential confounders.

There are several limitations in this study. First, because this was a pilot study, with a small sample size and a reduce time of intervention, we had limited ability to find significant changes in all variables. Although we found significant difference in balance and HRQL, probably we did not have adequate power to detect small or moderate improvement in the other secondary outcomes. The sample size in this study was limited by recruitment difficulties and time and financial restrictions. In addition, the participants were volunteers which may limit the generalizability to the population. Second, although the FAB scale is a practical balance assessment tool that is both valid and reliable, when used to assess multiple dimensions of balance in community-residing older adults (Rose et al., 2006), it is not a direct measure of balance. A combination of direct measures of balance, such as force platform, could be used in order to obtain a more accurate result.

Despite the limitations, this study showed that the assessment and intervention protocols turned out to be feasible. The results achieved, namely, the high test-retest reliability of the measurements, the high adherence and retention of the participants during the intervention, as well as, the change scores in balance verified immediately after the intervention, suggested that the necessary conditions are granted for a high quality research to answer to the efficacy hypothesis in a larger RCT. In this feasibility study we shifted the emphasis from sample size to focus on methodological quality, in order to achieve a trial with less bias. These results could be combined with those from similar studies and included in a meta-analysis (Schulz & Grimes, 2005).

Future Research

The ProBalance program has been shown to be feasible and to have a promising effect on balance scores of older adults, under the circumstances of a pilot study of a RCT. However, the program's efficacy needs to be evaluated in a RCT with a larger sample size and longer intervention period as well as follow-up.

Conclusions

The present study showed high levels of reliability for all variables. The protocols for assessments and for the intervention were fully applied, which illustrates the feasibility of the ProBalance program in the context of a pilot RCT. Eligibility rate was low (15%). However, all randomized participants (n=12) completed the assessments and intervention program, resulting in very high adherence and retention rates. The 4-week intervention was associated to improvements in clinical balance. These findings are supportive of further research on the efficacy of the ProBalance program. Nevertheless, inclusion criteria should be expanded in order to order to increase the eligibility rate.

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Chapter 6

The ProBalance Program improves balance and reduces fall risk in community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial.

Bridge

This chapter comprehends an article which reports the findings on the primary outcome of the main randomized controlled trial developed in the context of the present research. This article is entitled *“The ProBalance Program improves balance and reduces fall risk in community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial”.* This original research report argues whether this rehabilitation nursing intervention was effective in improving clinical balance of the older adults with balance impairments.

The preliminary results of this study were presented in a slide communication in the American College of Sports Medicine’s Annual Meeting and 5th World Congress on Exercise is Medicine® (May 27-31, 2014). An abstract was published on the leading multidisciplinary original research journal of the American College of Sports Medicine, namely, the *Medicine and Science in Sports and Exercise* (Impact Factor 4.475).

The final article is under review by co-authors for submission to the *International Journal of Nursing Studies*.

Abstract

This study aims to assess the effect of the ProBalance Program on balance in community-dwelling older adults from Madeira Island, Portugal. A randomized controlled trial included community-dwelling older adults, aged 65-85, with balance impairments. Participants were randomly allocated to an intervention group (IG, n = 27), and a wait-list control group (CG, n=25). The exercise program included gait, balance, functional training, strengthening, flexibility, and 3D training. The intervention was administered on a group basis by one trained rehabilitation nurse, in 90 min sessions, 2 days per week, for 12 weeks. The primary outcome was balance, assessed by the Fullerton Advanced Balance (FAB) scale. The time points for assessment were at 0 (pre-test), 12 (post-test), and 24 weeks (follow up). Changes in the total FAB scale scores after 12 weeks were 5.15 (SD = 2.81) for the IG and -1.45 (SD = 2.80) for the CG. After a follow-up, the change scores were -1.88 (SD = 1.84) and 0.75 (SD =2 .99 for IG and CG, respectively. Split-plot ANOVA design showed a significant interaction between group and time (F (2, 43) = 30.75, $p < 0.001$, Partial Eta Squared = 0.59) and for time (F (2, 43) = 9.65, p <0.001, Partial Eta Squared = 0.31), with both groups showing changes in the total FAB scale scores across the three time periods. The significant main effect comparing the two groups (F (1, 44) = 29.43, p < 0.001, Partial Eta Squared = 0.40) and the graphic representation showed a clear positive effect of the intervention when compared to usual care. This study demonstrated that the exercise program was effective in improving balance and reducing fall risk in a group of older adults with balance impairment, immediately after the intervention.

Key words: Rehabilitation nursing, ProBalance Program, Balance, Community-dwelling, Older adults.

Introduction

Balance impairment is one of the strongest modifiable risk factors for falls (Rubenstein & Josephson, 2002; Tinetti & Kumar, 2010; Deandrea et al., 2010), and an important independent predictor of the transition in status from non-faller to faller (Muir et al., 2010).

A recent review supports that some types of exercise related to gait, balance, coordination, functional tasks, strengthening exercise, 3D training (including tai chi, qi gong, dance, and yoga) and multiple exercise types are moderately effective in improving clinical balance of older adults, immediately after an intervention. Yet, the majority of previous research has targeted healthy older adults or frail older adults (Howe, Rochester, Neil, Skelton, & Ballinger, 2011). Therefore, further research is necessary to provide more robust evidence on this topic.

Theory-driven rehabilitation programs targeting important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness, have proven to be effective in reducing fall risk among older adults identified as moderate-to-high risk for falls (Rose, 2011). Improvements in balance of community-dwelling older adults with balance impairments are expected in further research on the effect of this type of multidimensional approach to balance. The ProBalance program was developed in response to this expectation, inspired by the FallProof Program (Rose, 2010). In this line, the present investigation aims to provide evidence of the effect of this group based exercise interventions targeting of community-dwelling older adults with balance impairments (moderate-to-high risk for falls) from Madeira Island, Portugal. A specific aim is to assess balance after a period of 12 weeks of detraining. From a rehabilitation nursing perspective, early identification of age-related changes and risk factors for falls affecting the older adults, such as balance impairments, and the delivery of targeted training are important to prevent older adults from progressing to more severe impairments or experiencing a serious fall. The knowledge provided is of major importance for nurses and other health professionals who work with older adults on a daily basis.

Method

Study design

A randomized controlled trial (RCT) was conducted to assess the effect of the ProBalance Program on balance of community-dwelling older adults with balance impairments from Madeira Island, Portugal. This RCT was prospectively registered in the Australian New Zealand Clinical Trials Registry Platform and the clinical trial registration number was ACTRN12612000301864.

Participants

The sample consisted of 177 relatively healthy community-dwelling men and women aged 65-85 years old. Participants were recruited from Madeira Island, Portugal, by advertising in a regional newspaper, posters, flyers with written information and social networks, as well as through presentations by the researcher to religious communities and social institutions in the city. Advertisement started in January 2012. Recruitment started in March 2012 and was completed in April 2012.

For participation, all volunteers were assessed for eligibility criteria in the project's laboratory in the University of Madeira, by a trained group of assessors (six Registered Nurses and an expert in the field of Gerokinesiology, who coordinated the group). Key inclusion criteria were: (1) to be community-dwelling older adult, aged 65 to 85 years old; (2) presenting a total FAB scale score higher than 25/40 and equal or lower than 30/40, or to present a total FAB scale score between 20 and 25/40, if not reporting falls in the past year; and (3) being able to walk independently. Exclusion criteria were: (1) to present cognitive impairment (assessed by the Mini Mental State Test), and (2) to have any significant co-morbidities that could preclude participation (such as acute illnesses, progressive neurological diseases, stroke, and unstable chronic conditions).

The optimal sample size was determined based on previous research and the results of our pilot study (4-week duration Mini-RCT), using G*Power3 (Faul, Erdfelder, Lang, & Buchner, 2007). A priori, repeated-measure ANOVA indicated that a total sample size of 48 was needed to achieve 95% power to detect the interaction effect size of 0.25 at the 0.05 level of significance. Although 0% attrition rate was found in our pilot study, a potential 8% attrition rate was considered for the main RCT and a total of 52 participants were targeted in this study.

A simple randomization process, using a computer random number generator, was used to allocate the eligible participants to one of the two groups, 1 and 2, later defined as the Intervention Group (IG) and the Control Group (CG). Clusters were considered in the randomization for couples and relatives. Blinding was used in the generation of the allocation sequence and in the assignment of the participants to the group. This task was carried out by an independent person.

Ethical approval for the ProBalance Project was granted by the Ethics Committee of the Health Service of the Autonomous Region of Madeira. Informed consent was provided by all participants at the enrolment phase. The intervention was provided for the control-group after the end of the trial due to ethical issues.

ProBalance intervention

ProBalance is a multiple exercise types rehabilitation nursing program, including balance, co-ordination and functional tasks training, gait training, strengthening and flexibility exercises and 3D training. Inspired by the FallProof Balance and Mobility Program (Rose, 2010), the ProBalance is a theory-driven program, adopting a multidimensional approach to balance and mobility in independent-living older adults with balance impairments. It targets important intrinsic risk factors associated with increased fall risk, such as impaired balance and gait, and muscle weakness (Rose, 2011).

The intervention was administered on a group basis by only one trained rehabilitation nurse, in 24 sessions, with 90-min duration, 2 days per week, for 12 uninterrupted weeks (between April and July 2012). The setting was the project's laboratory at the University. The exercise sessions included: (1) multisensory training, approaching visual, somatosensory and vestibular systems; (2) center of gravity control training; (3) proactive and reactive postural strategy training; (4) gait pattern enhancement and variation training; (5) strengthening and endurance exercise; and (6) flexibility training. The rationale for the development of this type of exercise intervention has been described elsewhere (Rose, 2010).

In the sessions, there were other independent members of the intervention team (trained university students) that assisted in the exercise preparation and kept security conditions next to the older adults during exercise performance (1:1 ratio). Aiming to enhance adherence of the participants, two additional educational sessions were delivered in the beginning and in the middle of the intervention, with 45-min duration each. This educational component addressed general aspects of fall prevention (risk factors and consequences of falls in older adults and importance of motivation in the adherence to fall-prevention interventions). Since the CG was a wait-list CG, during the intervention period, this group maintained usual care, which excluded any specific balance training.

Outcome measures

The primary outcome in this study was balance, assessed by the Fullerton Advanced Balance (FAB) scale, a validated and reliable multidimensional balance assessment tool that is designed to be used when assessing the balance of higher functioning older adults (Klein, Fiedler, & Rose, 2010; Rose, Lucchese, & Wiersma, 2006). Total scores and change scores for the main outcome were analyzed. The change in fall risk was analyzed taking into account that 1-point change in total FAB scale score is associated to an 8% change in fall risk (Hernandez & Rose, 2008). The time points for assessment were at 0 (pre-test), 12 (post-test), and 24 weeks (follow up). Participants were assessed by one blinded and independent assessor. Prior to this RCT and after specific training, test-retest reliability of the assessments was established in a pilot study (12 participants, 2 assessments with 1-week interval). Intra-class correlation coefficient (R) was 0.885 for the FAB Scale.

Baseline assessments

In this study, other baseline characteristics were assessed, namely: (1) demographic characteristics (gender, age, education); (2) clinical characteristics (number of falls and number of medication); (2) Cognition, [Mini-Mental State (Folstein, Folstein, & McHugh, 1975; portuguese version by Guerreiro et al, 1994)]; (3) Balance [Fullerton Advanced Balance Scale (Rose, et al., 2006), gait velocity, derived from 30-foot walk test (Rose, 2010); Falls Efficacy Scale (Tinetti, Richman, & Powell, 1990; portuguese version by Melo, 2011)]; (4) Functional fitness components [chair stand and arm curl, sit and reach, and 6-minute walk tests, height and weight (Rikli & Jones, 2001)]; (6) Physical activity (PA) (Voorrips, Ravelli, Dongelmans, Deurenberg, & Staveren, 1991; portuguese version by Azevedo, 2009); (7) Health-Related Quality of Life (HRQL) (Ware & Sherbourne, 1992; portuguese version by Ribeiro, 2005). In addition to the fact that all protocols were validated, in our pilot study, reliability of all measures was also verified (Intra-class correlation coefficient (R) between 0.689 and 0.987).

Statistical analysis

Statistical analysis included descriptive statistics and a mixed-ANOVA (between groups within subjects). This mixed between-within subjects analysis of variance was conducted to assess the impact of the intervention/control on participants' total scores on the FAB Scale, across the three time periods (pre-test, post-test and 12-week follow-up). Data analysis assumptions were verified and respected. P value was set at 0.05. Data were analyzed using the IBM SPSS statistics 20 computer package.

Results

A total of 177 older adults were assessed for potential enrollment. Of these, only 52 older adults were eligible and randomly allocated to the IG (n = 27) and to the wait-list control group (CG) receiving usual care (n = 25). Only 46 participants completed the study (IG, n = 26; CG, n = 20). The implementation of the intervention followed the initial protocol. Adherence for the participants who completed the study, assessed by the proportion of sessions attended, was 100%. No adverse events (i.e. falls) or side effects were associated with the exercise intervention or the assessments. However, other events led to losses, as described in the diagram flow (Figure 6.1).

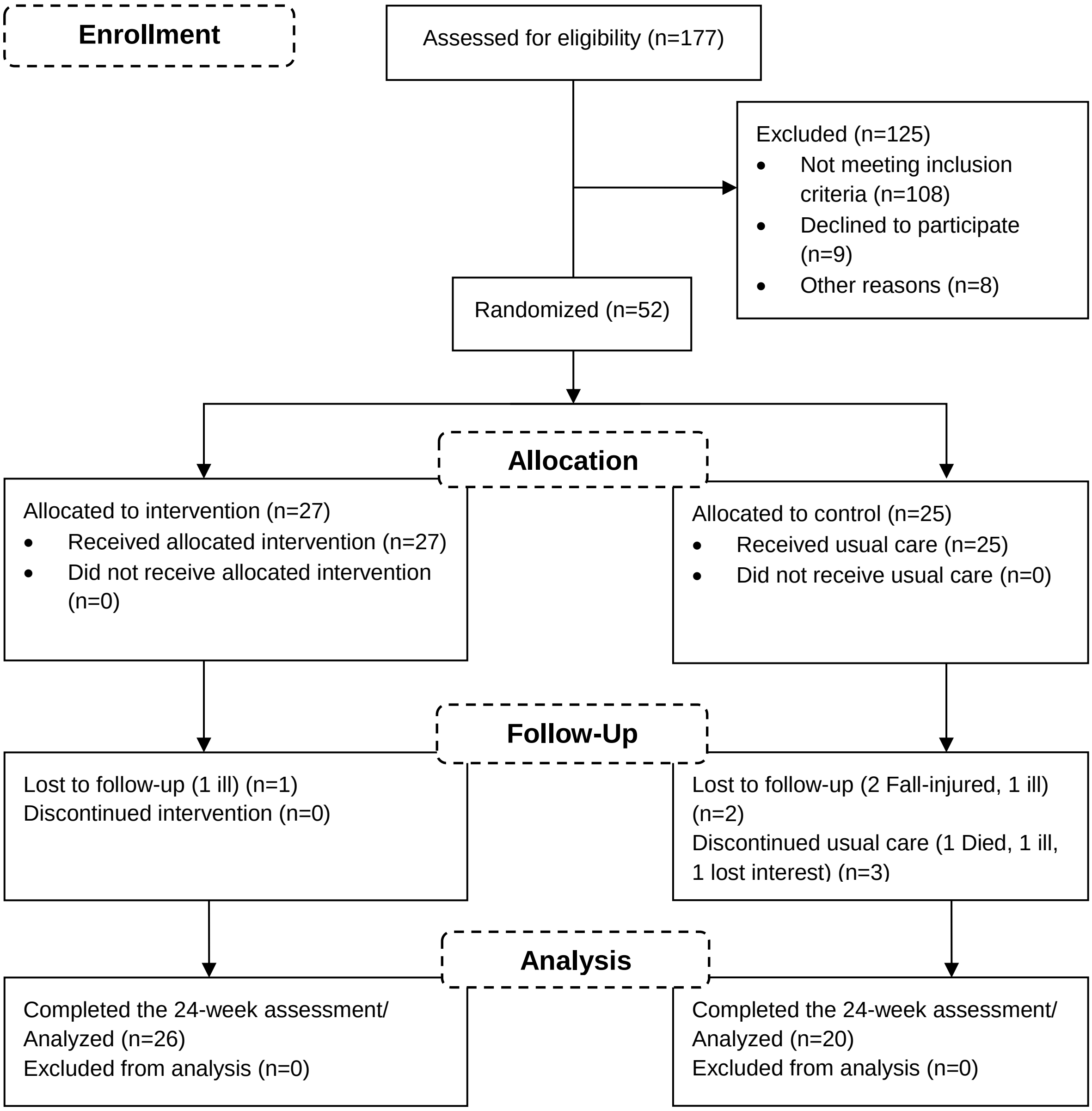

Figure 6.1 Participant flow through the phases of the randomized controlled trial.

Through a simple randomization process, two groups with similar characteristics were created. Participants' characteristics at baseline are summarized in Table 6.1.

No statistical significant differences were observed between CG and IG for any baseline characteristics, except for physical activity total score and leisure time physical activity.

Table 6.1 Participants' characteristics at baseline: sociodemographic, clinical, cognition, balance, functional fitness, physical activity and health-related quality of life.

Variables	CG (n =20)	IG (n = 26)	*p*
Sociodemographic			
Gender (female)	22 (88.0%)	24 (88.9%)	-
Age (y)	74.06±4.60	73.15±4.57	0.511
Education (y)	4.05±2.52	4.15±2.29	0.885
Clinical			
Number of medications (n)	5.50±3.02	5.81±2.55	0.710
Number of falls in the past year (n)	0.45±0.60	0.54±0.86	0.687
Cognition			
Mini-Mental State (score)	26.45±3.10	27.38±2.25	0.242
Balance			
Total FAB scale (score)	26.95±2.67	27.58±2.77	0.444
Gait velocity at the preferred speed (m/sec)	1.16±0.25	1.28±0.17	0.073
Gait velocity at the maximum speed (m/sec)	1.53±0.34	1.67±0.21	0.110
Falls Efficacy Scale (score)	86.90±18.35	90.88±10.75	0.361
Functional fitness			
Chair stand test (n)	13.05±3.28	13.62±2.70	0.525
Arm curl test (n)	15.00±3.49	16.08±3.64	0.317
6-minute walk test (m)	455.36±97.72	490.62±65.73	0.151
Physical activity			
Household (score)	1.74±0.29	1.89±0.45	0.181
Sports (score)	1.33±1.48	1.07±1.97	0.625
Leisure time (score)	2.32±2.78	5.28±4.41	**0.008**
Total (score)	5.38±2.50	8.24±4.92	**0.014**
Health-related quality of life			
Sf-36 physical component (score)	190.71±56.69	220.76±62.47	0.099
Sf-36 mental component (score)	211.25±76.86	231.43±103.65	0.452
Total Sf-36 (score)	401.96±115.73	452.19±151.48	0.225

CG, control group; IG, intervention group; FAB, Fullerton Advanced Balance; †absolute and relative frequencies; ‡values are means and standard deviations.

Effect of the intervention

Descriptive statistics for total FAB Scale scores at baseline and after the intervention are presented in Table 6.2. After 12 weeks (post-test), the change scores in the total FAB scale mean are 5.15 points in the IG and -1.45 points in the CG. Considering that a 1-point change in total FAB scale score is associated to a 8.0% change in fall risk (Hernandez & Rose, 2008), the change scores after the 12-week intervention represent a 41.2% decrease in fall risk for the IG. At the same time point, the CG presented an increase in fall risk by 11.6%.

All participants were assessed 12 weeks after the terminus of the intervention – detraining period. Descriptive results for the follow up are presented in Table 6.3. The change scores are -1.88 and 0.75 points, for IG and CG, respectively. These change scores represent a 15.0% increase in fall risk for the IG and a 6.0% decrease in fall risk for the CG. In both, CG and IG, changes reached statistical significance.

Table 6.2 Findings on the outcome measure at baseline and after the intervention by group: control and intervention.

	Control group (n=20)				Intervention group (n=26)			
Variable	Pre-test	Post-test	Δ score	p	Pre-test	Post-test	Δ score	p
Total FAB scale score	26.95±2.67	25.50±3.36	-1.45±2.80	0.032	27.58±2.77	32.73±2.11	5.15±2.81	<0.0001

FAB, Fullerton Advanced Balance; Δ score, change between pre- and post-test.

Table 6.3 Findings on the outcome measure at baseline and after the intervention by group: control and intervention.

	Control group (n = 20)				Intervention group (n = 26)			
Variable	Post-test	Follow up	Δ score	p	Post-test	Follow up	Δ score	p
Total FAB scale score	25.50±3.36	26.25±3.89	0.75±2.99	0.276	32.73±2.11	30.85±3.18	-1.88±1.84	<0.0001

FAB, Fullerton Advanced Balance; Δ score, change between post-test and follow up.

Effect size estimates

A mixed between-within subjects analysis of variance was conducted to assess the impact of the intervention/control on participants' total scores on the FAB Scale, across the three time periods (pre-test, post-test and 12-week follow-up). This analysis demonstrates the significant interaction between the group and time (Wilk's Lambda = 0.41, F (2, 43) = 30.75, p < 0.001, Partial Eta Squared = 0.59). There was a statistically significant effect for time (Wilk's Lambda = 0.69, F (2, 43) = 9.65, p <0.001, Partial Eta Squared = 0.31), with the both groups showing changes in the total FAB scale scores across the three time periods. The significant main effect comparing the two groups (F (1, 44) = 29.43, p <0.001, Partial Eta Squared = 0.40) and the graphic representation (Figure 6.2) shows that there was a difference in the efficacy of the intervention and usual care (CG). In addition, the results show a very large effect size, assuming the guidelines proposed by Cohen (1988).

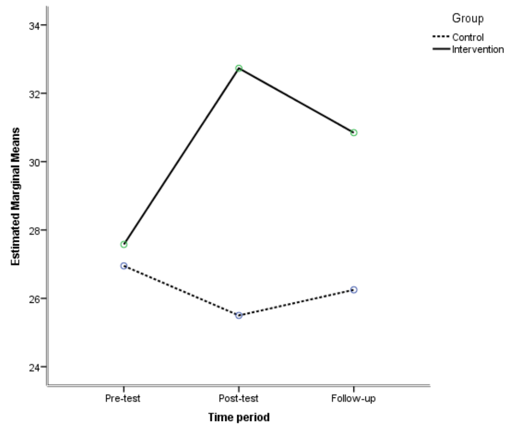

Figure 6.2 Graphic representation of the results from the mixed between-within subjects analysis of variance (group vs time), showing the change in FAB scale total scores over time for the IG and CG.

Discussion

The general aim of this study was to examine the effect of the Probalance program in a clinical measure of balance in community-dwelling older adults. Two similar groups were evaluated in this RCT. The group that was randomly allocated to the 12-week intervention showed significant gains in balance after the intervention, contrary to their peers that were randomly allocated to the CG. After the intervention (post-test), the total FAB scale mean score increased by 5.15 points in the IG, while there was a decrease of 1.45 points in the CG. At follow up, the change scores were -1.88 and 0.75 points, for IG and CG, respectively. Besides there was a decrease in the IG, results did not reach the baseline scores. Overall, both groups showed changes in the total FAB scale scores across the three time periods; nevertheless opposite results were found for the IG and CG (as seen in figure 2), which is explained by the significant interaction between the group and time, the significant effect of time, and the significant main effect comparing the two groups.

Similarly, Westlake and Culham (2007), in a randomized controlled trial aimed to assess the effect of an 8-week theory-driven exercise intervention based on the FallProof Program, found post-intervention improvements in the FAB scale score (a 4-points increase for the IG and a 1-point increase for CG, which received education only). Contrary to our results, Westlake and Culham (2007) report the maintenance of FAB Scale scores by the participants in the IG at follow up. In regard to the increase FAB scale scores in the CG at follow-up, a similar finding was also reported by Westlake and Culham (2007) after the intervention. A possible explanation for these results could be a training effect after repeated assessments using the FAB Scale, as well as, an increased awareness of the participants in relation to balance and fall prevention.

Although different measures of balance were used as outcome in the majority of randomized trials reviewed, multiple exercise type interventions have been shown to be associated to significant improvements in other composite measures of balance (Howe et al., 2011). Change score of 17.80 for the IG (n = 21) and 0.40 for the CG (n = 23) in the Berg Balance Scale (BBS) were found by Worm et al. (2001), after a 12-week intervention. Other studies, also using the also the BBS as an outcome measure, reported significant improvements in mean differences between control and intervention after immediately intervention (Beyer et al., 2007; Sykes & Ling, 2004).

Another interesting finding of this study was that the total FAB scale mean score increased and moved away from the cut-off point of 25 in the IG, which was predictive of the faller status, as described by Hernandez and Rose (2008). On the other hand, after 12 weeks, the participants in the CG continued to present FAB scores equal or lower than 25 points. Another valuable finding is that, although there was a decrease at follow up for the IG, the total FAB scale score did not reach the baseline situation. These findings highlight the clinical significance of the effect of the ProBalance intervention, namely through its contribution to reduce fall risk.

The statistical significance of the effect of the intervention demonstrated responsiveness to training in the participants in the IG; however, there was evidence of a short-lasting effect after the exercise intervention finished. The current study added evidence to support the conclusion stated by Howe et al. (2011) who observed that positive balance effects were only evident while engaging in the intervention.

Strengths

There is previous evidence that exercise interventions can improve balance in community-dwelling older adults. Yet, the majority of previous research has targeted healthy older adults or frail older adults (Howe et al., 2011). The results of this study provide evidence to the existing research on the effects of group based exercise interventions targeting a balance-screened group of community-dwelling older adults. From a rehabilitation nursing perspective, early identification of balance impairments and delivery of specific training are important preventive interventions, since many older adults only seek health professional advice when serious fall-related injuries happen. Therefore, assessment and intervention at an early stage may prevent community-dwelling older adults from progressing to more severe impairments or experiencing a serious fall (Yang et al., 2012). Besides exercise programs that target the intrinsic risk factors associated with increased fall risk have been shown to be effective in a number of randomized controlled trials conducted over the past two decades (Rose, 2011). The present study aimed to respond to the need for research on theory-driven rehabilitation programs that focus on manipulating individual, task, and environmental constraints concurrently, as suggested by Rose and Clark (2000). Other advantage of our study was the high adherence to the sessions in the participants who completed the study (100%). This may be indicative of the high acceptability and motivation of the participants, related to this innovative intervention.

Limitations

Three limitations of this study should be addressed. First, balance was assessed using an indirect method; however, in opposition to direct measures of balance, such as force platform assessments; FAB does not require expensive equipment and are easily reproduced in community settings (Howe et al., 2011). Since the present research has focused on assessing balance in independent community-dwelling older adults and that it was desirable a valid and reliable field method, FAB was chosen as the main outcome. FAB scale is a relatively new multidimensional balance assessment tool that is designed to assess balance of higher functioning older adults. It was primarily developed by Debra Rose at California State University, Fullerton (Rose, Lucchese, & Wiersma, 2006), and has been shown to have good psychometric properties (Klein, Fiedler, and Rose, 2010). Second, participants were volunteers who responded to advertisement, which may limit the generalizability to the wider population. Finally, and besides other balance measures have been assessed in the ProBalance project, this study only reported the total FAB score. Further research will be conducted in order to fulfill these requirements.

Future directions

The ProBalance program has been shown to produce an expected positive effect on balance under the circumstances of an RCT. However, the program's long-term efficacy, its effectiveness in "real world" clinical settings, and its cost-effectiveness remain to be evaluated. Consequently, further research is needed to accomplish these goals.

Conclusions

This study demonstrated that ProBalance exercise program was effective in improving balance and reducing fall risk by 40% in a group of older adults with balance impairment, immediately after the intervention. The large effect size found indicated that the improvements could be attributed to the intervention. Future research should focus on long term-efficacy and include pragmatic trials to assess the effectiveness and cost-effectiveness of this intervention in "real world" clinical settings.

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Chapter 7

The effect of the ProBalance Program in strength and gait of community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial.

Bridge

This chapter comprehends an article reporting the effects of the ProBalance intervention in major balance-related outcomes. The article is entitled "*The effect of the ProBalance Program in strength and gait of community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial"*. This original report addresses the efficacy of this rehabilitation nursing intervention in improving strength of the lower and upper body, gait velocity, stride length and cadence in older adults with balance impairments, in the context of the ProBalance main randomized controlled trial.

This article is under review by co-authors for submission to the *Journal of the American Geriatrics Society*.

Abstract

This study aims to assess the effect of a rehabilitation nursing program - the ProBalance Program on strength and gait of community-dwelling older adults. A randomized controlled trial included community-residing older adults, aged 65-85, screened for balance impairments. Participants were randomly allocated to an intervention group (IG, n=27), and a wait-list control group receiving usual care (CG, n=25). Only 46 participants completed the study (IG, n=26; CG, n=20). The exercise program included gait, balance, functional training, strengthening and endurance, flexibility, and 3D training. The intervention was administered on a group basis by one trained rehabilitation nurse, in 90 min sessions, 2 days per week, for 12 weeks. Strength was assessed by the chair stand and arm curl tests, and gait, through gait velocity, stride length and cadence, at preferred and maximum speed, derived from the 30-foot walk test. The time points for assessment were at 0 (pre-test), 12 (post-test), and 24 weeks (follow up). Statistical analysis included descriptive statistics, t-test statistics and mixed-ANOVAs between groups within subjects.

No significant differences were seen in the CG across the two time points (pre- and post-test) for strength and gait. The IG showed significant improvements in the strength of the lower (Δ score = 2.42, SD = 1.70; $p<0.001$) and upper body (Δ score = 2.23, SD = 2.55; $p<0.001$), immediately after the 12-week intervention. At follow-up, there was a decrease in both lower and upper body strength (Δ score = -1.15, SD = 1.76; $p=0.003$; Δ score = -1.73, SD = 1.97; $p<0.001$, respectively). The mixed-ANOVA, controlling for physical activity and age, showed a large interaction effect between group and time for chair stand and arm curl tests. No statistically significant differences were seen for gait parameters at preferred speed, for both groups. At maximal speed, there were significant differences and a large effect size for group in gait velocity in the IG (Δ score = 0.21, SD = 0.20; $p<0.001$) and large interaction effects in cadence (Δ score = 0.22, SD = 0.312; $p=0.002$). Overall, for strength and gait, an improvement was observed from pre-test to post-test and a decrease in the follow up for the IG. However, the decrease at follow up in the strength of the lower body and cadence did not reach the baseline scores.

This study highlighted that the ProBalance program was associated to improvements in strength, and gait velocity and cadence at maximal speed.

Key words: Rehabilitation nursing, ProBalance Program, Balance, Strength, Gait, Community-dwelling, Older adults.

Introduction

Falls in community-dwelling older adults and their impact on the individual and their families are a major public health concern. Research has addressed this problem and several risk factors have been associated with falls. Strength and gait impairments, along with balance deficits, are the strongest modifiable risk factors for falls (Rubenstein & Josephson, 2002; Tinetti & Kumar, 2010; Deandrea et al., 2010). Theory-driven exercise programs targeting balance and gait, and muscle strength, have proven to be effective in reducing fall risk among older adults identified as moderate-to-high risk for falls (Rose, 2011). Although different balance-related outcomes were used, in several randomized trials, multiple exercise type interventions have been shown to be associated to significant improvements in strength and gait (Cadore, Rodríguez-Mañas, Sinclair, & Izquierdo, 2013; Howe et al., 2011; Lopopolo, Greco, Sullivan, Craik, & Mangione, 2006).

The ProBalance program is a rehabilitation nursing program inspired by the FallProof Program (Rose, 2010) and adopts a multidimensional approach to balance and mobility. Promising results, namely significant improvements in balance of community-dwelling older adults with balance impairments have previously been identified after the ProBalance intervention (Gouveia et al., 2014). In this line, we also expect an improvement in strength and gait. Therefore, this study aims to provide evidence of the effect of this group based exercise intervention targeting of community-dwelling older adults with balance impairments from Madeira Island, Portugal.

From a rehabilitation nursing perspective, early identification of age-related changes and risk factors for falls affecting the older adults, such as balance impairments, and the delivery of targeted training are important complex interventions to prevent older adults from progressing to more severe impairments or experiencing a serious fall.

Method

Study design

A randomized controlled trial (RCT) was conducted to assess the effect of a rehabilitation nursing program - the ProBalance Program - on balance-related outcomes, namely, strength and gait, of community-dwelling older adults with balance impairments from Madeira Island, Portugal.

This RCT was prospectively registered in the Australian New Zealand Clinical Trials Registry Platform and the clinical trial registration identification was ACTRN12612000301864.

Participants

The sample consisted of 177 relatively healthy community-dwelling men and women aged 65-85 years old, recruited from Madeira, Funchal. The advertisement phase started in January 2012. Advertisement was done through a regional newspaper, posters, flyers with written information and social networks, as well as through presentations by the researcher to religious communities and social institutions in the city. The recruitment phase started in March 2012 and was completed in April 2012.

All volunteers were assessed for eligibility criteria in the project's laboratory in the University of Madeira, by a trained group of assessors (six Registered Nurses and an expert in the field of Gerokinesiology, who coordinated the group).

Inclusion criteria were: (1) to be community-dwelling older adult, aged 65 to 85 years old; (2) presenting a total FAB scale score higher than 25/40 and equal or lower than 30/40, or to present a total FAB scale score between 20 and 25/40, if not reporting falls in the past year; and (3) being able to walk independently.

Participants were excluded, when specific conditions were identified: (1) to present cognitive impairment (assessed by the Mini Mental State Test), and (2) to have any significant co-morbidities that could preclude participation (such as acute illnesses, progressive neurological diseases, stroke, and unstable chronic conditions).

The optimal sample size calculation for this trial was based on previous research, and the results of our pilot study (4-week duration Mini-RCT), using G*Power3 (Faul, Erdfelder, Lang, & Buchner, 2007). A priori, repeated-measure ANOVA indicated that a total sample size of 48 was needed to achieve 95% power to detect the interaction effect size of 0.25 at the 0.05 level of significance in strength. Although 0% attrition rate was found in our pilot study, a potential 8% attrition rate was considered for the main RCT and a total of 52 participants were targeted in this study. Cut-off points provided by Cohen (1988) were used for interpretation of effect sizes.

A computer random number generator was used in a simple randomization process. Consequently, eligible participants were allocated to one of the two groups, 1 and 2, later defined as the Intervention Group (IG) and the Control Group (CG). Clusters were considered in the randomization for couples and relatives. Blinding was used in both the generation of the allocation sequence and in the assignment of the participants to the group by an independent person.

Ethical approval for the ProBalance Project was granted by the Ethics Committee of the Health Service of the Autonomous Region of Madeira in January 2011. Informed consent was provided by all participants at the enrolment phase. The same intervention was conducted for the CG after the end of the trial due to ethical issues.

ProBalance intervention

ProBalance is a rehabilitation nursing intervention targeting older adults with balance impairments. It is a multiple exercise types program, including balance, co-ordination and functional tasks training, gait training, strengthening exercise, flexibility training and 3D training. It was inspired by the FallProof Balance and Mobility Program (Rose, 2010), a theory-driven program, that adopts a multidimensional approach to balance and mobility in independent-living older adults with balance impairments. In this type of intervention, impaired balance and gait, and muscle weakness are targeted, since they are important intrinsic risk factors associated with increased fall risk (Rose, 2011).

The group-based ProBalance intervention was administered by only one trained rehabilitation nurse, in 24 unique sessions (90-min duration each), 2 days per week, during 12 uninterrupted weeks (from April to July 2012). The setting was the project's laboratory at the University.

Each exercise session included: (1) multisensory training, approaching visual, somatosensory and vestibular systems; (2) center of gravity control training; (3) proactive and reactive postural strategy training; (4) gait pattern enhancement and variation training; (5) strengthening and endurance exercise; and (6) flexibility training. The rationale for this type of exercise intervention has been described elsewhere (Rose, 2010).

During the sessions, there were other independent members of the intervention team (trained university students) that assisted in the exercise preparation and kept security conditions during exercise performance (1:1 ratio).

Aiming to enhance adherence of the participants, two additional educational sessions were delivered in the beginning and in the middle of the intervention (45-min duration each). This educational component addressed general aspects of fall prevention, namely: (1) risk factors and consequences of falls in older adults, and (2) the importance of motivation in the adherence to exercise interventions.

The control was a wait-list CG. During the intervention period, the controls maintained standard care, which excluded any specific balance training.

Outcome measures

Balance-related outcomes involved strength, assessed by the chair stand and arm curl tests (Rikli & Jones, 2001), and gait parameters, considering gait velocity (m/sec), stride length (m/stride), and cadence (steps/sec), at preferred and maximum speed, derived from 30-foot walk test (Rose, 2010). The time points for assessment were at 0 (pre-test), 12 (post-test), and 24 weeks (follow up). Blinded assessments were done by independent trained assessors. In the preparation of this RCT, specific training was delivered to all assessors and test-retest reliability was verified in a pilot study (12 participants, 2 assessments with 1-week interval).

Baseline Assessments

Baseline characteristics of all participants were assessed. This characteristics included: (1) demographic and clinical information (gender, age, education, number of falls and number of medication evaluated by questionnaire); (2) Cognition, assessed by the Mini-Mental State (Folstein, Folstein, & McHugh, 1975; Portuguese version by Guerreiro et al, 1994); (3) Balance [Fullerton Advanced Balance Scale (Rose, Lucchese, & Wiersma, 2006), gait velocity, stride length and cadence, derived from 30-foot walk test (Rose, 2010)]; Falls Efficacy Scale (Tinetti, Richman, & Powell, 1990; Portuguese version by Melo, 2011); (4) Functional fitness components [chair stand and arm curl, sit and reach, and 6-minute walk tests, height and weight (Rikli & Jones, 2001)]; (6) Physical activity (PA) (Voorrips, Ravelli, Dongelmans, Deurenberg, & Staveren, 1991; portuguese version by Azevedo, 2009); (7) Health-Related Quality of Life (HRQL) (Ware & Sherbourne, 1992; portuguese version by Ribeiro, 2005). Instruments and protocols have been validated for the Portuguese population, as referenced. Reliability of all measures was verified in the pilot study. For all measures, intra-class correlation coefficient (R) ranged between 0.689 and 1.000.

Statistical analysis

Statistical analysis included descriptive statistics, t-test statistics and mixed between-within subjects analysis of variance (mixed-ANOVA). The t-test statistics were used to assess differences between groups and the mixed-ANOVA was used to assess the effect of the intervention/control on participants' total scores on the outcome variables, across the three time periods (pre-test, post-test and 12-week follow-up), controlling for PA scores and age at baseline. Partial Eta Squared values were reported as measures of effect size. Normality and data analysis assumptions were verified. The IBM SPSS statistics 20 computer package was used for all calculations. In this study, analysis included all participants who completed the study.

Results

A sample of 177 community-dwelling older adults was evaluated for potential enrollment. Only 52 older adults were eligible and were randomly allocated to an intervention group (IG, n=27) and to a wait-list control group, receiving usual care (CG, n=25). Only 46 older adults completed the trial (IG, n=26; CG, n=20), and the intervention was implemented following the initial protocol.

In this study, there were no adverse events (i.e. falls) or side effects associated with the exercise intervention or the assessments to report. However, six losses happened due to other causes, as described in the diagram flow (Figure 7.1). All participants who concluded the study were engaged in the totality of the intervention sessions (100% adherence).

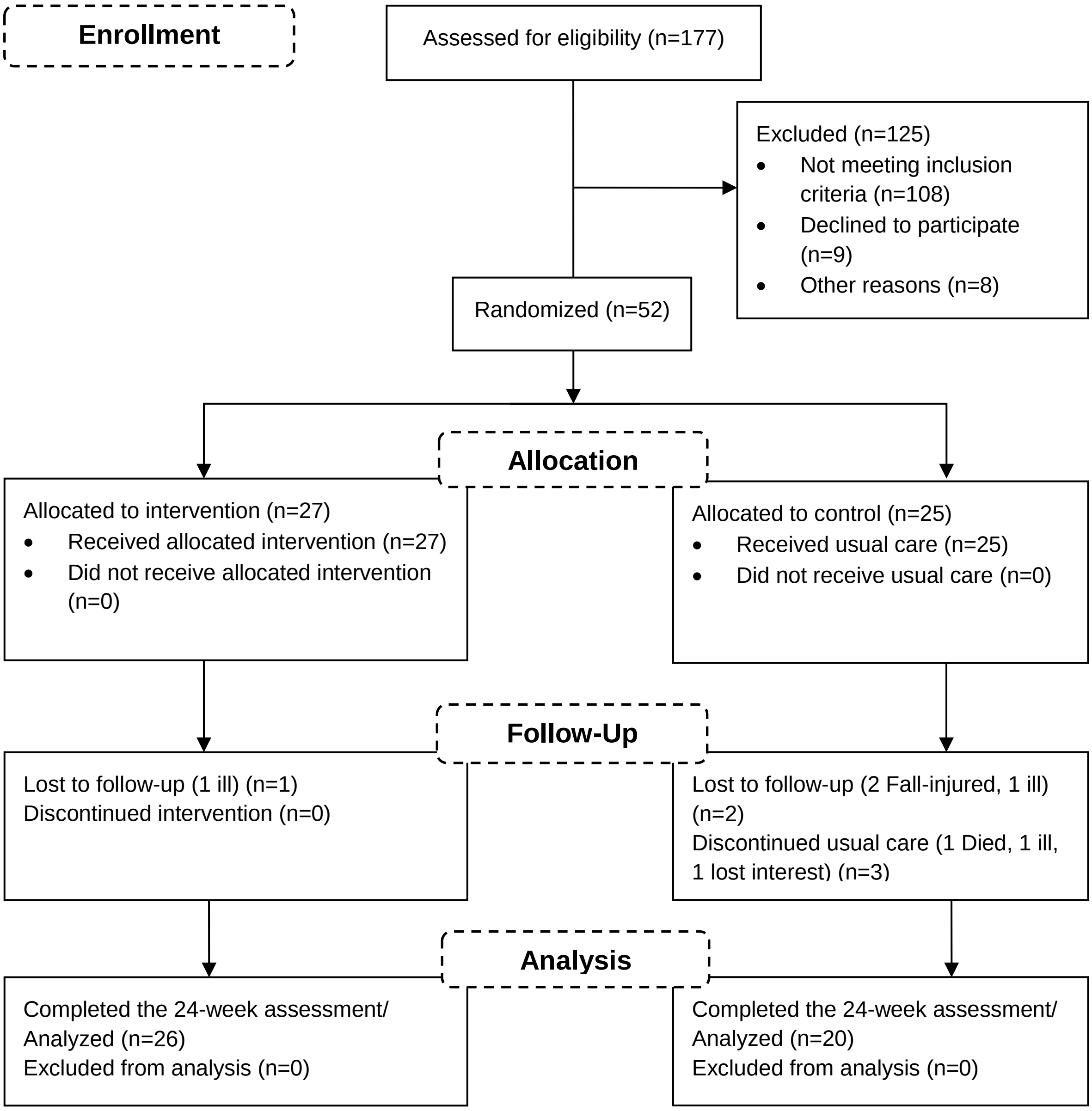

Figure 7.1 Participant flow through the phases of the randomized controlled trial.

Baseline characteristics of the participants

A simple randomization process was used to create two similar groups (1 and 2, identified afterwards as CG and IG). Table 7.1 describes the baseline characteristics of the participants who completed the study (n=46). For stride length and PA (total and leisure time) there were statistically significant differences between the IG and the CG at baseline. Participants in the IG show higher scores than their peers from the CG.

Table 7.1 Participants' characteristics at baseline: sociodemographic and clinical characteristics, cognition, balance, functional fitness, physical activity and health-related quality of life.

Variables	CG (n =20)	IG (n = 26)	*p*
Sociodemographic			
Gender (female)	90.00%	88.50%	-
Age (y)	74.06±4.60	73.15±4.57	0.511
Education (y)	4.05±2.52	4.15±2.29	0.885
Clinical			
Number of medications (n)	5.50±3.02	5.81±2.55	0.710
Number of falls in the past year (n)	0.45±0.61	0.54±0.86	0.697
Cognition			
Mini-Mental State (score)	26.45±3.16	27.38±2.25	0.242
Balance			
Total FAB scale (score)	26.95±2.67	27.58±2.77	0.444
Gait velocity at the preferred speed (m/sec)	1.16±0.24	1.28±0.17	0.090
Gait velocity at the maximum speed (m/sec)	1.53±0.34	1.67±0.21	0.110
Stride length at preferred speed (m/stride)	1,17±0,18	1,26±0,13	0.050*
Stride length at maximum speed (m/stride)	1,34±0,19	1,48±0,14	0.005*
Cadence at preferred speed (steps/sec)	1,98±0,19	2.02±0,18	0.432
Cadence at maximum speed (steps/sec)	2.27±0,28	2.26±0,20	0.880
Falls Efficacy Scale (score)	86.90±18.35	90.88±10.75	0.361
Functional fitness			
Chair stand test (n)	13.05±3.28	13.62±2.70	0.525
Arm curl test (n)	15.00±3.50	16.08±3.64	0.317
6-minute walk test (m)	455.36±97.72	490.62±65.73	0.151
Height (cm)	153.89±6.34	152.98±7.07	0.653
Weight (kg)	71.06±11.91	65.87±12.82	0.168
Physical activity			
Household (score)	1.74±0.29	1.89±0.45	0.181
Sports (score)	1.33±1.48	1.07±1.97	0.625
Leisure time (score)	2.31±2.78	5.27±4.41	0.008*
Total (score)	5.38±2.50	8.24±4.92	0.014*
Health-related quality of life			
Sf-36 physical component (score)	190.71±56.69	220.76±62.47	0.099
Sf-36 mental component (score)	211.25±76.86	231.43±103.65	0.452
Sf-36 total (score)	401.96±115.73	452.19±151.48	0.225

Values are mean±standard deviation for quantitative variables and relative frequencies (%) for qualitative variables.
FAB, Fullerton Advanced Balance.

Description of effects

Descriptive statistics for the strength tests and gait parameters at preferred and maximal speed at pre-test and post-test are presented in table 7.2.

After 12-weeks (post-test), the mean change score in the chair stand test was 0.25 in the CG and 2.42 in the IG. Similar results were seen in the arm curl test, with a mean change score of 0.20 in the CG and 2.23 in the IG. In both strength tests, only in the IG, the improvements reached statistical significance.

In gait parameters at preferred speed similar changes were seen in both the CG and the IG. Overall, no significant changes were found. In gait parameters at maximal speed, statistically significant changes were seen in gait velocity and cadence, only for the IG. For gait velocity, the mean change score was 0.07 in the CG and 0.21 in the IG; while for cadence, the change score was -0.07 in the CG and 0.22 in the IG.

Participants were also assessed 12 weeks after the terminus of the intervention (follow up). Descriptive results for the follow up are presented in table 7.3.

After the 12-week follow up, changes were seen in both groups in the strength tests. In the chair stand test, the mean change score was 0.55 in the CG and -1.15 in the IG. For the arm curl test, the mean change score was 0.60 in the CG and -1.73 in the IG. In both strength tests, only in the IG, changes reached statistical significance, describing a significant decrease in the lower and upper body strength with detraining.

In gait parameters at preferred speed and at maximal speed, modest or no changes were seen in both the CG and the IG, however, in both groups, changes did not reach statistical significance.

Table 7.2 Findings on the outcome measures at baseline and after the intervention by group.

	Control Group (n = 20)				Intervention Group (n = 26)			
Variables	Pre-test	Post-test	Δ score	p	Pre-test	Post-test	Δ score	p
Strength								
Chair stand test (n)	13.05±3.14	13.30±3.61	0.25±1.68	0.514	13.41±2.86	16.04±2.55	2.42±1.70	<0.001
Arm curl test (n)	15.00±3.40	15.20±5.04	0.20±2.91	0.762	16.00±3.59	18.31±2.33	2.23±2.55	<0.001
Gait at preferred speed†								
Velocity (m/sec)	1.16±0.25	1.24±0.20	0.08±0.19	0.075	1.28±0.17	1.33±0.13	0.06±0.21	0.164
Stride length (m/stride)	1.16±0.18	1.22±0.13	0.05±0.12	0.062	1.25±0.14	1.29±0.11	0.03±0.13	0.207
Cadence (Steps/sec)	1.98±0.19	2.04±0.20	0.06±0.20	0.222	2.03±0.18	2.07±0.13	0.04±0.18	0.268
Gait at maximal speed†								
Velocity (m/sec)	1.53±0.34	1.60±0.33	0.07±0.22	0.171	1.67±0.21	1.88±0.21	0.21±0.20	<0.001
Stride length (m/stride)	1.33±0.18	1.49±0.39	0.15±0.42	0.130	1.48±0.14	1.53±0.14	0.04±0.12	0.082
Cadence (Steps/sec)	2.27±0.28	2.19±0.35	-0.07±0.34	0.355	2.26±0.20	2.47±0.23	0.22±0.32	0.002

Values are means and standard deviations; †Walk a distance of 15 meters; Δ score, change between pre- and post-test.

Table 7.3 Findings on the outcome measures after the intervention and at follow up by group.

	Control Group (n = 20)				Intervention Group (n = 26)			
Variables	Post-test	Follow up	Δ score	p	Post-test	Follow up	Δ score	p
Strength								
Chair stand test (n)	13.30±3.61	13.85±2.60	0.55±2.19	0.275	16.04±2.55	14.88±1.77	-1.15±1.76	0.003
Arm curl test (n)	15.20±5.04	15.80±3.56	0.60±2.74	0.340	18.31±2.33	16.58±2.35	-1.73±1.97	<0.001
Gait at preferred speed†								
Velocity (m/sec)	1.24±0.20	1.26±0.20	0.01±0.15	0.730	1.33±0.13	1.33±0.16	0.00±0.15	0.866
Stride length (m/stride)	1.22±0.13	1.23±0.13	0.01±0.09	0.668	1.29±0.11	1.29±0.08	0.00±0.10	0.992
Cadence (Steps/sec)	2.04±0.20	2.04±0.18	0.00±0.19	0.969	2.07±0.13	2.06±0.17	-0.01±0.18	0.716
Gait at maximal speed†								
Velocity (m/sec)	1.60±0.33	1.58±0.27	-0.02±0.20	0.702	1.88±0.21	1.83±0.22	-0.05±0.17	0.166
Stride length (m/stride)	1.49±0.39	1.41±0.21	-0.08±0.41	0.396	1.53±0.14	1.52±0.12	0.00±0.11	0.899
Cadence (Steps/sec)	2.19±0.35	2.24±0.18	0.05±0.34	0.519	2.47±0.23	2.41±0.27	-0.06±0.27	0.273

Values are means and standard deviations; †Walk a distance of 15 meters; Δ score, change between post-test and follow up.

Effect size estimates

A mixed between-within subjects analysis of variance was conducted to assess the impact of the intervention/control on all outcome measures, across the three time periods (pre-test, post-test and 12-week follow-up), controlling for PA and age.

In the chair stand test, this analysis demonstrates that there was a significant interaction between the group and time (Wilk's Lambda = 0.70, F (2, 41) = 8.75, p = 0.001, Partial Eta Squared = 0.30), with the both groups showing improvements over time. No statistically significant main effects were found for time (Wilk's Lambda = 0.97, F (2, 41) = 0.66, p = 0.52, Partial Eta Squared = 0.03) or for group (F (1, 42) = 1.20, p = 0.28, Partial Eta Squared = 0.03) in this balance-related outcome.

In the arm curl test, results from the mixed-ANOVA showed also that there was a significant interaction between the group and time (Wilk's Lambda = 0.79, F (2, 41) = 5.57, p = 0.007, Partial Eta Squared = 0.21), with the both groups showing improvements in the upper body strength. Again, no significant main effects were found for time (Wilk's Lambda = 0.92, F (2, 41) = 1.72, p = 0.19, Partial Eta Squared = 0.08) or group (F (1, 42) = 0.87, p = 0.36, Partial Eta Squared = 0.02) in the arm curl test. A graphic representation of the mixed between-within subjects analysis of variance (group vs time, with PA and age as covariates) is shown in Figure 7.2 for chair stand (a) and arm curl test (b).

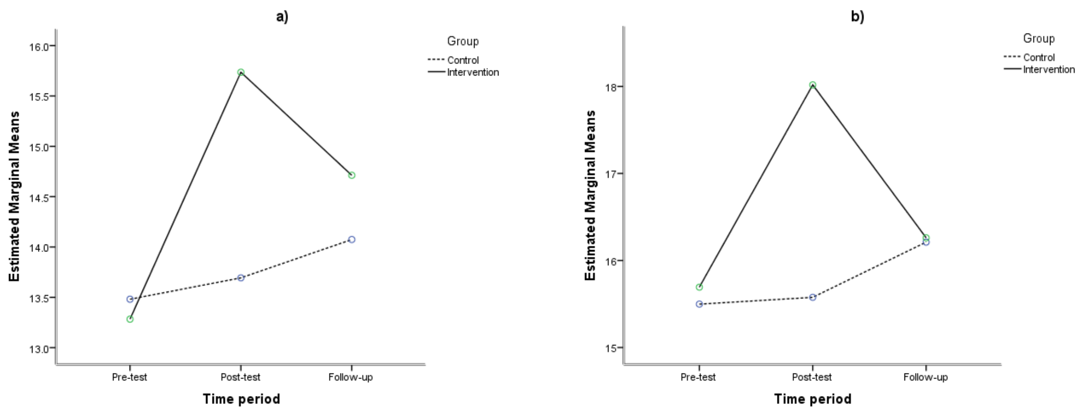

Figure 7.2 Graphic representation of the results from the mixed between-within subjects analysis of variance (group vs time, with PA and age as covariates), showing the change in the chair stand (a) and arm curl tests (b), over time for the CG and IG.

For gait parameters at preferred speed, the same analysis demonstrates that there were no significant main effects. At maximal speed, results show that there were significant effects in gait velocity and cadence. In gait velocity, there was no significant interaction between the group and time (Wilk's Lambda = 0.87, F (2, 40) = 2.91, p = 0.06, Partial Eta Squared = 0.13) nor a significant effect for time (Wilk's Lambda = 0.99, F (2, 40) = 0.19, p = 0.82, Partial Eta Squared = 0.01). In opposition, there was a significant main effect comparing the two groups (F (1, 41) = 6.45, p = 0.02, Partial Eta Squared = 0.14), suggesting that there was large effect size. In cadence, there was a significant and large interaction effect between the group and time (Wilk's Lambda = 0.82, F (2, 40) = 4.53, p = 0.02, Partial Eta Squared = 0.19). However, there was no statistically significant effect for time (Wilk's Lambda = 0.95, F (2, 40) = 1.09, p = 0.34, Partial Eta Squared = 0.05) and no significant effect for group (F (1, 41) = 3.86, p = 0.06, Partial Eta Squared = 0.09). The graphic representation of these results is shown in figure 7.3.

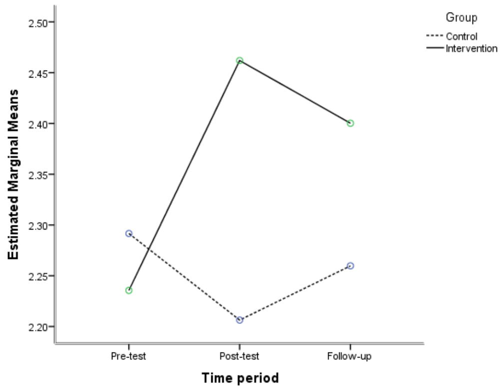

Figure 7.3 Graphic representation of the results from the mixed between-within subjects analysis of variance (group vs time, with PA and age as covariates), showing the change in cadence at maximal speed, over time for the CG and IG.

Discussion

The purpose of this study was to examine the effect of the ProBalance program in a set of balance-related outcomes, namely, strength and gait in a group of community-dwelling older adults screened for balance impairments. Two similar groups were assessed in this RCT, in a total of three assessments (pre-test, post-test and follow up). While no significant differences were seen in the CG across the three time points, the IG showed significant improvements in the strength of the lower and upper body, immediately after the 12-week intervention. Furthermore, the IG experienced a significant decrease in strength after follow up. In regard to gait parameters at preferred speed, no significant differences or effects were seen. Yet, at maximal speed, our results showed that there were significant differences in gait velocity and cadence in the IG.

These results are in agreement to those of previous research on the effect of different interventions on balance-related outcomes, showing that multiple exercise type interventions were associated to significant improvements in strength and gait (Cadore, Rodríguez-Mañas, Sinclair, & Izquierdo, 2013; Howe et al., 2011), however, inconsistent research findings on the effect of exercise on gait of community-dwelling older adults have been described (Lopopolo, Greco, Sullivan, Craik, & Mangione, 2006).

Binns and Taylor (2011) have developed a 24-week duration controlled trial focused on the effect of an exercise program targeting strength and balance (the Otago Exercise Program) in older adults (n=37), delivered by nurses in a community care setting. Only pre- and post-test assessments were considered in this study and outcomes included lower body strength, assess by the chair stand test, and mobility, assessed by gait velocity at maximal speed. Contrary to our results, this research found no improvements in lower body strength (change score = 0.00) in the IG, while modest improvements were seen in the CG (change score = 0.35). In regard to gait velocity, Binns and Taylor (2011) found negative change scores for both groups (-0.16 in the IG and -0.06 in the CG). Nevertheless, changes did not reach statistical significance.

Hartmann, Murer, Bie and de Bruin (2009) have also investigated the effect of physical exercise combined with foot gymnastics on strength and gait performance in older adults (n=56), in the context of an RCT. Although using different instruments, similarly to our results, in this study there were significant increases in lower body muscle power, gait velocity and cadence in stable floor. These results parallel our findings. On the other hand, Hartmann et al. (2009) found significant improvements in step length, which was not verified in the current research. Halvarsson, Olsson, Farén, Pettersson and Stahle (2011) also found significant positive changes in gait velocity and cadence at maximal speed after group-based balance training program. In this research, significant changes in cadence at preferred speed were also seen.

Independent of the type of interventions and instruments used, while some RCTs have failed to find significant differences in strength (Bird, Hill, & Fell, 2012) and gait velocity (Barnett et al, 2003) after the exercise intervention, others showed significant improvements on the studied variables, supporting our results (Beyer et al., 2007; Behpoor, Darabi, Hojatoleslami, Bayat, & Ghanbari, 2012; Granacher et al., 2012).

In regard to strength, our results demonstrate that the effects of the ProBalance intervention on strength were short-lasting, since significant decreases in the lower and upper body were seen after the exercise intervention ceased. In face of evidence of these short-lasting effects of exercise, the current study adds evidence to support the recommendation that muscle-strengthening activities involving major muscle groups, should be performed by older adults on 2 or more days a week, in addition to the recommended 150 minutes of moderate-intensity aerobic physical activity per week or 75 minutes of vigorous-intensity aerobic physical activity throughout the same time period (WHO, 2010).

In the present research, the CG did not show significant deterioration of any of the outcome measures during the trial. Binns and Taylor (2011), suggest that 24-weeks may be an insufficient period of time to observe the manifestations of physiological age-related changes. Nevertheless, Hartmann et al. (2009) have found a deterioration trend in strength and gait after 12-weeks. A possible explanation for this result could be the effect of PA and age, which have been controlled for in our analysis.

Strengths

There is evidence that exercise interventions can improve balance-related outcomes in community-dwelling older adults. However, while most studies have targeted healthy or frail older adults (Howe et al., 2011), this study adds evidence on the effects of multiple type exercise interventions targeting a balance-screened group of community-dwelling older adults. An advantage of this prehabilitation approach, including assessment and intervention at an early stage, could be preventing community-dwelling older adults from progressing to more severe impairments or experiencing a serious fall as suggested by Yang et al. (2012). Besides many types of exercise programs have been shown to effectively improve balance of older adults in several randomized controlled trials conducted in the last decades (Howe et al., 2011), the need for further research on the effect of theory-driven rehabilitation programs that focus on the concurrent manipulation of individual, task-related, and environmental constraints has been reported (Rose & Clark, 2000). In response to this need, this study adds evidence on the beneficial effect of a theory-driven intervention targeting balance and mobility of older adults, based in the FallProof Program (Rose, 2010).

Easy reproducibility of the assessments in clinical practice was also desired. To grant this requirement, functional performance-based tests were used as outcome measures in our study. Although they are not direct measures of strength or balance, functional measures are typically used in older adults as they better relate to performance in activities of daily living (Binns & Taylor, 2011), do not require expensive equipment and are easily reproduced in community settings (Howe et al., 2011).

Other advantage of our study was the very high adherence of the participants to the intervention and the inexistence of adverse events related to the participation in the intervention, suggesting that the program was motivating and safe for the participants.

Limitations

Three limitations of this study should be stated. First, the participants in our study were volunteers who responded to advertisement, which can limit the generalizability of the results. Second, in spite of the randomization, there were differences in baseline characteristics of the participants. In order to overcome this weakness, PA entered as covariate in the statistical.Third, other balance-related outcomes could be useful to better understand the effects of this complex intervention, however, besides other core outcome measures have been assessed in the ProBalance project, part of these data have been reported elsewhere (Gouveia et al., 2014).

Future directions

The ProBalance program has been shown to produce improvements in strength, and gait velocity and cadence at maximal speed, under the circumstances of a small scale RCT. Still, research is needed on the program's long-term efficacy, its effectiveness at the community level, and its cost-effectiveness. Further research will be conducted in order to fulfill these requirements.

Conclusions

The results of the present study showed that the participation in the 12-week rehabilitation nursing program – the ProBalance program was associated to improvements in strength, gait velocity and cadence at maximal speed. Short-lasting effects on strength were verified at follow-up, with significant decreases in the scores of strength tests. Overall, the large effect sizes suggest that the improvements could be attributed to the intervention.

This study adds evidence to previous research on the effect of an exercise intervention on balance-related outcomes, supporting the known evidence that multiple exercise type interventions are associated to significant improvements in strength and gait. However, further research should target a longer intervention period, its long term-efficacy and proceed to pragmatic trials to assess the effectiveness and cost-effectiveness of this intervention in clinical settings.

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Chapter 8

Conclusion

8.1 Overview of the study findings
8.2. Limitations and strengths of the research
8.3. Implications for clinical practice and future directions
8.4. References

Bridge

In this chapter, we address the main conclusions of this research, describing the main findings, as well as the limitations and strengths of the study.

At last, relevance of this clinical research is explained, presenting the implications for nursing clinical practice in the gerontological rehabilitation context and pointing future directions for nursing research in this field.

8.1. Overview of the study findings

Falls in community-dwelling older adults and their impact on the individual and their families are a major public health concern. Research has addressed this problem and several risk factors have been associated with falls. Among, those, balance, strength and gait impairments are the strongest modifiable risk factors for falls (Rubenstein & Josephson, 2002; Tinetti & Kumar, 2010; Deandrea et al., 2010).

From a rehabilitation nursing perspective, specifically in view of the “Functional consequences theory” (Miller, 2012), and considering the potential effects of prehabilitation exercise interventions on balance control, designing and testing an effective balance intervention was found relevant becoming the central topic of this research.

On this basis, with the ProBalance project - *Prehabilitation and Rehabilitation Nursing: Balance/ fall risk in the community-dwelling older adult, Randomized Controlled Trial* - we intended to contribute to the overall knowledge on the effect of a rehabilitation nursing interventions targeting community-dwelling older adults screened for balance impairments. The ProBalance program is a theory-driven program designed with this objective, inspired by the FallProof Balance and Mobility Program (Rose, 2010), adopting a multidimensional approach to balance and mobility, targeting important intrinsic risk factors associated with increased fall risk, such as impaired balance, gait, and muscle weakness (Rose, 2011).

The purpose of this research was: (1) to assess the feasibility and safety of the ProBalance program; and (2) to assess the effect of the ProBalance program in a group of community-dwelling older adults with balance impairments, on balance, muscular strength and gait parameters, when compared to a control group after a 12 week duration intervention and 12 weeks follow up.

Besides recognizing that the feasibility of randomized controlled trials is in many cases compromised in clinical nursing settings (Halberg, 2009), this was the gold standard study design to address this type of problem. Therefore, an RCT aimed to assess the effect of the ProBalance program on balance in community-dwelling older adults with balance impairments, from Madeira Island, Portugal.

In face of the identification of the complexity of this rehabilitation nursing approach to older adults with balance impairment, the ProBalance program was developed following the MRC (2008) guidance for developing, evaluating and implementing complex interventions.

This thesis reported the research process throughout eight chapters, which included a review a literature, the method, a theoretical article, the research report of the first study that comprised the pilot RCT and two research reports addressing results from the second original study, the main RCT.

The brief literature review addressed the theoretical and scientific background to our research, a description of the nursing perspective in the care of older adults, based on the "Functional consequences theory for promoting wellness in older adults" and the concept of "Prehabilitation". Through a dissertation on the current knowledge about falls in community-dwelling older adults, balance and balance related-outcomes, balance assessment and interventions aimed at improving the balance, we recognized that emphasis should be given to the identification of age-related changes and risk factors affecting the older adults, as a guide for a targeted intervention in rehabilitation nursing practice aiming to promote functional gains. This knowledge provided rational for the ProBalance intervention.

The first article (chapter 4), entitled "Therapeutic exercise in Gerontological Rehabilitation: A literature analysis", was written during the review of literature that preceded this research. This analysis of the literature allowed us to describe the beneficial effect of various therapeutic exercise interventions, in posture, gait and functional fitness of older adults, justifying its relevance in gerontological rehabilitation. In the revised studies, special relevance was also given to balance as a related outcome. Although 11 studies were reviewed in search for these relationships, there were no references to the intervention of a rehabilitation nurse specialist in this field. These findings reinforced that more research was needed to define the specificity of therapeutic exercise in gerontological rehabilitation, and assess the effect of nursing interventions in gerontological rehabilitation nursing, so that its feasibility, safety and benefits are ensured, before implementation in clinical context. This way, nursing research can contribute and play a major role facing the challenge of global ageing and the knowledge provided will be of impact on clinical practice (Halberg , 2006).

The second article in this thesis (chapter 5) is entitled "The ProBalance program for improving balance in older adults: A pilot study". It comprises an original research report from the pilot study aimed to investigate the feasibility of the ProBalance program in a group of community-dwelling older adults living in Madeira, Portugal. Test-retest reliability for all measures, recruitment, adherence and retention and short-term changes in balance-related outcomes were assessed.

In a sample 88 older adults, 12 were eligible and were randomized to two similar groups (n=12). The protocols for assessments and for the intervention were fully applied, with no adverse events associated to the intervention. Eligibility rate was low (15%) and the attrition rate was null. Intraclass correlation coefficient (R) for the total FAB scale score was 0.885. In gait parameters, R ranged between 0.717 (velocity) and 0.799 (stability ratio). For functional fitness, R was between 0.689 (arm curl) and 0.987 (back scratch). High R values were also found for HRQL- physical (0.984) and mental (0.930), cognition

(0.789), falls efficacy (0.940), and habitual physical activity (0.978). Only in the IG, there was a statistically significant increase in total FAB scale score (p = 0.007), arm curl (p = 0.041), and HRQL- physical (p = 0.019) and mental (p = 0.013) from baseline to post-intervention. In the CG, significant changes were seen in cadence (p = 0.024) and chair-sit-and-reach test (p = 0.029). No statistically significant differences were observed in the remaining variables, in both, IG or CG.

This study demonstrated that the ProBalance program was feasible and safe, and a promising effect on balance scores of older adults was verified. The findings suggested the need for further research on the efficacy of the ProBalance program. Nevertheless, inclusion criteria need to be expanded in order to increase the eligibility rate. A larger sample and a longer intervention period were necessary to meet this goal.

The third article (chapter 6), entitled “The ProBalance program improves balance and reduces fall risk in community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial”, aimed to examine the effect of the ProBalance program in the primary outcome, clinical of balance in community-dwelling older, measured by FAB scale. In a sample 177 older adults, 52 were randomized to two similar groups and were evaluated and considered in a per protocol analysis (n=46). The time points for assessment were at 0 (pre-test), 12 (post-test), and 24 weeks (follow up). Changes in the total FAB scale scores after 12 weeks were 5.15 (SD = 2.81) for the IG and -1.45 (SD = 2.80) for the CG. After a follow-up, the change scores were -1.88 (SD = 1.84) and 0.75 (SD = 2.99) for IG and CG, respectively. The mixed-ANOVA showed a significant interaction between group and time (F (2, 43) = 30.75, p < 0.001, Partial Eta Squared = 0.59) and for time (F (2, 43) = 9.65, p < 0.001, Partial Eta Squared = 0.31), with both groups showing changes in the total FAB scale scores across the three time periods, but in different directions. The significant main effect comparing the two groups (F (1, 44) = 29.43, p < 0.001, Partial Eta Squared = 0.40) and the graphic representation showed a clear positive effect of the intervention when compared to usual care.

This study demonstrated that the ProBalance exercise program was effective in improving balance and reducing fall risk by 40% in a group of older adults with balance impairment, immediately after the intervention. Besides there was a decrease in balance scores in the IG at follow up, results did not reach the baseline scores.

The last article included in this thesis (chapter 7), entitled “The effect of the ProBalance Program in strength and gait of community-dwelling older adults from Madeira Island, Portugal: A randomized controlled trial”, intended to examine the effect of the ProBalance program in a set of balance-related outcomes (strength and gait parameters), in a group of community-dwelling older adults screened for balance impairments.

In the same sample 177 older adults, 52 were randomized to two similar groups and were evaluated and considered in a per protocol analysis (n=46).

No significant differences were seen in the CG across the two time points (pre- and post-test) for strength and gait. The IG showed significant improvements in the strength of the lower body, with a change score of 2.42 (SD = 1.70), and the upper body, with a change score of 2.23 (SD = 2.55), immediately after the 12-week intervention. At follow-up, there was a decrease in both lower and upper body strength, with change scores of -1.15 (SD = 1.76) and -1.73 (SD = 1.97), respectively. The mixed-ANOVA, controlling for physical activity and age, showed a large interaction effect between group and time for chair stand and arm curl tests. No statistically significant differences were seen for gait parameters at preferred speed, for both groups. At maximal speed, there were significant differences and a large effect size for group in gait velocity in the IG (change score = 0.21, SD = 0.20) and large interaction effects in cadence (change score = 0.22, SD = 0.312).

This study highlighted the efficacy of the ProBalance program on strength and gait, namely, since it was associated to significant improvements in strength of the lower and upper body; and gait velocity and cadence at maximal speed.

Overall, this research succeeded in demonstrating that the ProBalance Program, a multidimensional rehabilitation nursing intervention, was feasibility and safe for community-dwelling older adults from Madeira, Portugal, in the context of a pilot RCT. Also the efficacy of this intervention was confirmed in the context of a larger RCT, namely in regard to balance and fall risk and other balance-related outcomes assessed. Based on the findings from hypothesis testing, we can state that all hypotheses were verified. Therefore, the following conclusions can be derived from the results:

(1) The group of community-dwelling older adults involved in ProBalance program had significantly higher levels of balance and lower risk for falling when compared with the group that did not receive the ProBalance intervention, after a 12 week duration intervention and 12 week follow up (H1);

(2) The group of community-dwelling older adults involved in ProBalance program had higher levels of muscular strength (lower body and upper body) when compared with the group that did not receive the ProBalance intervention, after a 12 week duration intervention and 12 week follow up (H2);

(3) The group of community-dwelling older adults involved in the ProBalance program had better results in gait parameters when compared with the group who did not receive ProBalance intervention, after a 12 week duration intervention and 12 week follow up (H3).

8.2. Limitations and strengths of the research

This research comprised two studies. First, a small scale pilot RCT was developed to test feasibility of the ProBalance program and allow the modelling of the research. The main RCT followed this research, integrating the knowledge drawn from this first study.

Awareness of the limitations of this research is important for an adequate interpretation of our study findings. Therefore, four main limitations in this research should be addressed: (1) the participants in both studies were volunteers who responded to advertisement, which can limit the generalizability of the results; (2) although balance-related outcomes were assessed using valid and reliable instruments, it consisted in indirect methods of assessment, which limit the comprehension and generalizability of results; (3) the reduced the time of intervention and the short term follow up could have limited the magnitude of the effects of the ProBalance detected in this research; and (4) although this study aimed primarily to assess efficacy of an intervention, a per protocol analysis might potentiate the results.

Besides these limitations, several strengths are to be mentioned: (1) the methodological quality of the research. The research process and methodological options followed the Medical Research Council guidance for the development, evaluation and implementation of complex interventions to improve health (MRC, 2008), and the CONSORT Statement (Boutron et al., 2008), as a guideline for reporting results from clinical trials; (2) both RCTs were prospectively registered; (3) assessment and intervention protocols turned out to be feasible; (4) inexistence of adverse events related to the participation in the intervention, ensuring safety of the intervention; (5) high test-retest reliability of the measurements was verified; (6) the assessors were trained professionals, including an expert in the field; (7) blinding was used in the randomization and assessment procedures; (8) the intervention was delivered by only one trained rehabilitation nurse, not involved in the assessments; (9) trained independent members of the intervention team kept security of the exercise in a 1:1 ratio; (10) easy reproducibility of the assessments and interventions were granted through the use of easily accessible and mobile materials; (11) high adherence and retention of the participants during the trials was achieved; and (12) the pertinence and clinical relevance of study findings.

8.3. Implications for clinical practice and future directions

The ProBalance program has been shown to produce significant and clinically relevant improvements in balance, strength, and gait velocity and cadence at maximal speed, under the circumstances of a randomized controlled trial. Therefore, this research has contributed to increased knowledge on the effect of a nursing intervention designed to improve clinical balance of community-dwelling older adults with balance impairments.

This new knowledge is of great importance for nursing sciences, due to the impact in clinical nursing, as a rationale for nursing interventions in the care of older adults. Therefore, dissemination in scientific journals and technical literature is necessary.
In face of evidence of the short-lasting effects of exercise found, the current study adds evidence to support recommendations that balance and muscle-strengthening activities should be performed by older adults in addition to general physical activity.
Future research should focus on the long term-efficacy of the ProBalance intervention. In addition, pragmatic trials should be developed to assess the effectiveness and cost-effectiveness of this intervention in "real world" clinical settings. Further research will be conducted in order to fulfill these requirements.

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Appendices

Appendix I – Sample exercise session plan

ProBalance Program

Prehabilitation and rehabilitation nursing: Balance and fall risk in community-dwelling older adults. Randomized controlled trial.

Sample ProBalance Session

First part

Position	**Exercise - Repetitions**
Sitting.	1. Head turns and tilts - 5 repetitions each side.
	2. Shoulder rotation - 5 repetitions.
	3. Arm rotations - 5 repetitions.
	4. Reach overhead - 5 repetitions.
Uprigth position, walking.	5. Walking exercises: • Heel digs • Toe taps • Knee lifts - 5 repetitions each.
Uprigth position, next to a chair.	6. V-steps - 5 repetitions.
Uprigth position, chair in front.	7. Side steps with arm movements - 10 repetitions.
Uprigth position, next to a chair.	8. Side lunges - 5 repetitions each side.
	9. Double side step with: • Heel digs • Toe taps • Knee lifts - 4 repetitions each foot.
	10. Cha Cha Cha steps - 4 repetitions each leading foot.

Second part

Position	Exercise - Repetitions
Uprigth position, next to a chair.	11. Weigth shifts with head turns – 5 repetitions each side.
	12. Forward steps on a bench - 5 repetitions each foot.
Uprigth position.	13. Crossing over two parallel lines in the floor - 2 repetitions per participants.

Third part

Position	Exercise - Repetitions
Uprigth position.	14. Volley ball in a circle - 5 touches per participant, in stable surface and then over foam.
Uprigth position, next to a chair.	15. Semi-tandem e Tandem over foam, tossing the ball with two hands - 5 repetitions each position.
Uprigth position.	16. Walking with disturbed vision. • Passing the ball to another participants; • Identify images and say the name of fruits and vegetables. • Wear dark glasses. - 2 repetition per participants.

Fourth part

Position	Exercise - repetitions
Uprigth position, walking.	17. Parachute exercise, walking with: • Heel digs; • Toe taps; • Knee lifts; • Squats; • Switch places; • Two teams, moving bean bags from one side to another. – 5 repetitions each position.

Position	Exercise - repetitions
	18. Crossing the street at the visual and verbal signal. - 2 repetition per participants.

Fifth part

Position	Exercise - repetitions
Sitting.	19. Arm curl with theraband - 8 repetitions each side.
	20. Arm extensions with theraband - 8 repetitions each side.
	21. Chest press with theraband - 8 repetitions each side.
Uprigth position, chair in front.	22. Heel raises - 5 sec, 8 repetitions each side.
	23. Toe raises - 5 sec, 8 repetitions each side.
Uprigth position, next to a chair.	24. Leg abduction - 5 sec, 8 repetitions each side.
	25. Leg flexion and extension - 5 sec, 8 repetitions each side.

Sixth part

Position	Exercise - repetitions
Sitting.	26. Lateral shoulder stretch - 15 sec, 2 repetitions each side.
	27. Reach over head - 15 sec, 2 repetitions.
	28. Chin to chest - 15 sec, 2 repetitions.
	29. Head turns - 15 sec, 2 repetitions.
	30. Neck side stretch - 15 sec, 2 repetitions.
	31. Trunk rotations - 15 sec, 2 repetitions.
Upright, with a chair.	32. Hamstring stretch - 15 sec, 2 repetitions.
Sitting	33. Calf stretch - 15 sec, 2 repetitions.
	34. Foot rotation - 2 repetitions each foot.

Materials:

1 Chair/ person; 1 Bench/ person; Foam Ball; 1 Foam/ person; 1 Pair of sunglasses/ person; Cards with images of fruits and vegetables; Rubber balls 10 cm diameter (1 per person); 1 Parachute; 20 Bean bags; 1 Theraband /person.

Appendix II – Educational session plan

ProBalance Program - Prehabilitation and rehabilitation nursing: Balance and fall risk in community-dwelling older adults. Randomized controlled trial.

Educational Session Plan

Theme: *Fall prevention for older adults in the community*

Clients: Participants of the randomized controlled trial

Duration: 45 minutes

Objectives:

(1) That participants learn about risk factors for falls in old age, consequences of falls in older adults and general fall prevention guidelines;

(2) That the participants are motivated for take part in targeted exercise sessions, focused on fall risk reduction through balance training.

Method:

(1) Structured overview and debate.

Contents:

(1) Risk factos for falls in old age;

(2) Consequences of falls in older adults;

(3) General fall prevention guidelines;

(4) Balance training and falls.

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Appendix III – Individual assessment file

(Portuguese Language)

Universidade do Porto
Instituto de Ciências Biomédicas
Abel Salazar

Prehabilitation and rehabilitation nursing: Balance/fall risk in community-dwelling older adults - Randomized Controlled Trial

Prehabilitation e enfermagem de reabilitação: Equilíbrio/risco de quedas em adultos idosos residentes na comunidade - Ensaio Clínico Controlado Randomizado

IDNR | | |.| | |

QUESTIONÁRIO DE CARACTERIZAÇÃO INDIVIDUAL

	Dia	Mês	Ano
Data de investigação			

	Dia	Mês	Ano
Data de nascimento			

Sexo Masculino ☐ Feminino ☐

Nome ______________________________

Tel. (casa) ____________________ Telemóvel ____________________

Outros contactos ____________________

Morada

Freguesia ______________________________

Av., Rua, etc. ______________________________

Nº Porta ou lote ☐☐☐☐☐☐ Andar ☐☐☐☐ Lado ☐☐☐☐

Código Postal ☐☐☐☐ – ☐☐☐ ____________________

Universidade do Porto
Instituto de Ciências Biomédicas
Abel Salazar

UNIVERSIDADE da MADEIRA

pro balance

IDNR | | | - | | |

Fullerton Advanced Balance (FAB) Scale

1. Permanecer de olhos fechados com os pés juntos

(0) - Incapaz de realizar e manter a posição correcta sem ajuda; (1) - Capaz de realizar a posição correcta sem ajuda, mas incapaz de manter a posição ou os olhos fechados mais de 10 segundos; (2) – Capaz de manter a posição correcta com os olhos fechados mais de 10 segundos, mas menos de 30 segundos; (3) – Capaz de manter a posição correcta com os olhos fechados durante 30 segundos, desde que haja supervisão próxima; (4) - Capaz de manter a posição correcta com os olhos fechados durante 30 segundos, com segurança.

2. Alcançar um objecto (lápis) no plano frontal

(0) – Incapaz de alcançar o lápis sem dar mais de dois passos; (1) – Capaz de alcançar o lápis, mas necessita de dar dois passos; (2) – Capaz de alcançar o lápis, mas necessita de dar um passo; (3) – Consegue alcançar o lápis sem mover os apoios, desde que haja supervisão próxima; (4) - Consegue alcançar o lápis sem mover os apoios, com segurança e sem ajuda.

3. Efectuar uma trajectória circular de 360º sobre um apoio

(0) – Necessita de ajuda manual enquanto roda; **(1) –** Necessita de supervisão próxima ou instruções enquanto roda; **(2) –** Capaz de rodar 360º, mas utiliza mais de 4 passos para completar a rotação, em ambas as direcções; **(3) –** Capaz de rodar 360º, mas incapaz de completar a rotação em 4 passos ou menos numa das direcções; **(4) –** Capaz de rodar 360º em segurança, dando 4 passos ou menos, em ambas as direcções.

4. Transpor um banco com 15cm de altura

(0) – Incapaz de colocar o apoio no banco sem perda de equilíbrio ou sem ajuda manual; **(1) –** Capaz de subir o banco com o membro inferior dominante, mas o outro membro contacta com o banco ou balança a perna, passando ao lado do banco, em ambas as direcções; **(2) –** Capaz de subir o banco com o membro inferior dominante, mas o outro membro contacta com o banco ou balança a perna, passando ao lado do banco, apenas numa direcção; **(3) –** Capaz de colocar correctamente o apoio no banco e transpor o outro apoio em ambas as direcções, mas requer supervisão próxima numa ou em ambas as direcções; **(4) –** Capaz de completar correctamente o apoio no banco e transpor o outro apoio, em ambas as direcções, em segurança e sem ajuda.

5. Dar 10 passos em linha recta

(0) – Incapaz de completar os 10 passos em linha recta sem ajuda; **(1) –** Capaz de completar os 10 passos com mais de 5 interrupções; **(2) –** Capaz de completar os 10 passos, com 3 a 5 interrupções; **(3) –** Capaz de completar os 10 passos, com 2 ou 1 interrupções; **(4) –** Capaz de completar os 10 passos, sem ajuda e sem interrupções.

6. Equilíbrio Sobre um apoio

(0) – Incapaz de tentar ou necessita de ajuda para prevenir a queda; **(1)** – Capaz de elevar o membro inferior sem ajuda, mas incapaz de manter a posição mais de 5 segundos; **(2)** – Capaz de elevar o membro inferior sem ajuda, e de manter a posição mais de 5 mas menos de 12 segundos; **(3)** – Capaz de elevar o membro inferior sem ajuda, e de manter a posição mais de 12 mas menos de 20 segundos; **(4)** – Capaz de elevar o membro inferior sem ajuda, e de manter a posição durante 20 segundos.

7. Permanecer de olhos fechados e a pés juntos numa superfície de espuma

(0) – Incapaz de subir para a superfície de espuma ou de manter a posição, sem ajuda, e de manter os olhos abertos; **(1)** – Capaz de subir para a superfície de espuma ou de manter a posição, sem ajuda, mas incapaz ou pouco disposto a fechar os olhos; **(2)** – Capaz de subir para a superfície de espuma ou de manter a posição, sem ajuda, com os olhos fechados durante 10 segundos ou menos; **(3)** – Capaz de subir para a superfície de espuma ou de manter a posição, sem ajuda, com os olhos fechados mais de 10 segundos e menos de 20 segundos; **(4)** – Capaz de r de subir para a superfície de espuma ou de manter a posição, sem ajuda, com os olhos fechados durante 20 segundos.

8. Saltar a dois pés

(0) – Incapaz ou pouco disposto a iniciar a impulsão para o salto a 2 pés, ou após a impulsão, um ou ambos os apoios permanecem no solo; **(1)** – Capaz de iniciar o salto a 2 pés, mas um pé antecipa-se ao outro na impulsão ou na chegada ao solo; **(2)** - Capaz de realizar o salto a 2 pés, mas incapaz de saltar mais longe que o comprimento dos próprios pés; **(3)** – Capaz de realizar o salto a 2 pés e atinge uma distância maior que o comprimento dos próprios pés; **(4)** – Capaz de realizar o salto a 2 pés e atinge uma distância maior que duas vezes o comprimento dos próprios pés.

9. Marchar com rotação simultânea da cabeça

(0) – Incapaz de dar 10 passos sem ajuda, com a rotação da cabeça a 30º no ritmo estabelecido; **(1)** – Capaz de dar 10 passos sem ajuda, mas incapaz de rodar a cabeça a 30º ao ritmo estabelecido; **(2)** – Capaz de dar 10 passos, mas desvia-se da linha recta enquanto roda a cabeça a 30º ao ritmo estabelecido; **(3)** – Capaz de dar 10 passos em linha recta, enquanto roda a cabeça ao ritmo estabelecido, mas roda a cabeça menos de 30º; **(4)** – Capaz de dar 10 passos em linha recta, sem ajuda, enquanto roda a cabeça a 30º e ao ritmo estabelecido.

10. Controlo da reacção postural

(0) – Incapaz de manter o equilíbrio; não reage ao nível dos apoios; requer ajuda para restabelecer o equilíbrio; **(1)** – Incapaz de manter o equilíbrio; dá menos de dois passos e requer ajuda para restabelecer o equilíbrio; **(2)** – Incapaz de manter o equilíbrio; dá mais de dois passos, mas consegue restabelecer o equilíbrio sem ajuda; **(3)** – Incapaz de manter o equilíbrio; dá dois passos, mas consegue restabelecer o equilíbrio sem ajuda; **(4)** – Incapaz de manter o equilíbrio, mas capaz de restabelecer o equilíbrio sem ajuda, só com um passo.

FAB Score Total:

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Sénior Fitness Test

Levantar e sentar na cadeira		n
Flexão do braço		n
2 minutos *step test*		n
Sit and reach (cadeira)		cm
Back scratch		cm
Shuttle run		seg
Andar 6 minutos		m

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30-foot walk test (9,24 metros)

Andar à velocidade preferida seg passos (n)

Andar à velocidade máxima seg passos (n)

Walkie-talkie test

Pára para responder

Não pára para responder

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AVALIAÇÃO
CLÍNICA GERAL

Pressão Arterial (BP) - Na posição de deitado (3 avaliações) e, seguidamente, sentado (3 avaliações).

	1ª Avaliação	2ª Avaliação	3ª Avaliação	4ª Avaliação	5ª Avaliação	6ª Avaliação	
Sistólica (SBP)							mmHg
Diastólica (DBP)							mmHg
Frequência Cardíaca							bpm

Glicose (GLI)		mg/dl
Colesterol (CHOL)		
Total (TC)		mg/dl
HDL		mg/dl
LDL		mg/dl
Triglicerídios (TRIGL)		mg/dl

Obesidade e gordura abdominal

Perímetro da cintura (WACI)		cm
Perímetro da anca (HACI)		cm
Rácio cintura / anca		
Altura (HT)		cm
Peso Corporal (WT)		kg
Índice de massa corporal		kg/m^2

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MINI-MENTAL TEST

Folstein, Folstein & McHugh (1975)

Estado Mental

Vou fazer-lhe algumas questões. A maior parte são fáceis.
Tente responder o melhor que for capaz.

Orientação no Tempo	0	1
Em que ano estamos?	☐	☐
Em que mês estamos?	☐	☐
Em que dia do mês estamos?	☐	☐
Em que estação do ano estamos?	☐	☐
Em que dia da semana estamos?	☐	☐

Orientação no Espaço	0	1
Em que país estamos?	☐	☐
Em que distrito vive?	☐	☐
Em que terra vive?	☐	☐
Em que casa estamos?	☐	☐
E que andar estamos?	☐	☐

Agora, vou dizer-lhe 3 palavras. Queria que as repetisse e que tentasse decorá-las, porque dentro de alguns minutos vou pedir-lhe que me diga essas 3 palavras.
As palavras são: PÊRA, GATO, BOLA. Repita as 3 palavras.

(Repetir todas as palavras até serem totalmente aprendidas, num máximo de 6 tentativas. Se as palavras não forem aprendidas não se pode fazer a prova de evocação.)
Registar as tentativas.

Pêra	☐	☐	☐	☐	☐	☐
Gato	☐	☐	☐	☐	☐	☐
Bola	☐	☐	☐	☐	☐	☐

Retenção	0	1
Pêra	☐	☐
Gato	☐	☐
Bola	☐	☐

Atenção e Cálculo

Agora, peço-lhe que me diga quantos são 30 menos 3, e que ao número encontrado volte a subtrair 3, até eu lhe dizer para parar.

(Parar ao fim de cinco respostas. Se fizer um erro na subtracção, mas continuar a subtrair correctamente a partir do erro, conta-se como um único erro.)

	0	1
27	☐	☐
24	☐	☐
21	☐	☐
18	☐	☐
15	☐	☐

Se o sujeito não conseguir executar a tarefa faz-se, em alternativa, uma outra:

Vou dizer-lhe uma palavra e queria que me dissesse essa palavra letra por letra, mas ao contrário, isto é, do fim para o princípio.
A palavra é : PORTA.

	0	1
A	☐	☐
T	☐	☐
R	☐	☐
O	☐	☐
P	☐	☐

Se o sujeito for analfabeto, faz-se em alternativa:

Vou dizer-lhe 3 números e queria que me dissesse esses 3 números, mas ao contrário, isto é, do último para o primeiro. Os números são: 5, 9, 2.

	0	1
2	☐	☐
9	☐	☐
5	☐	☐

Evocação

Agora veja se me consegue dizer quais foram as 3 palavras que lhe pedi há pouco para decorar.

	0	1
Pêra	☐	☐
Gato	☐	☐
Bola	☐	☐

Nomeação

Como se chama isto?

		0	1
Mostrar um:	Relógio de Pulso	☐	☐
	Lápis	☐	☐

Repetição

		0	1
Repita a frase:	O rato rói a rolha	☐	☐

Compreensão Verbal

Vou dar-lhe uma folha de papel. Quando eu lhe entregar o papel, pegue nele com a sua mão direita e dobre-o ao meio e coloque-o no chão.

	0	1
Mão	☐	☐
Meio	☐	☐
Chão	☐	☐

Compreensão leitura

Leia e cumpra o que diz neste cartão*.
(Mostrar a frase num cartão. Se o sujeito for analfabeto, o examinador deverá ler-lhe a frase.)

	0	1
Cumpre	☐	☐

Escrita

Escreva uma frase.
(Deverá ter sujeito, verbo e ter sentido. Erros gramaticais e troca de letras não são relevantes)

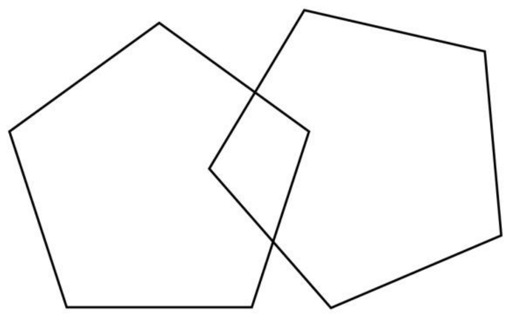
	0	1
Escreve	☐	☐

Desenho

Copie o desenho que lhe vou mostrar neste cartão *.
(Deverão estar presentes 10 ângulos e 2 deles devem estar intersectados. Tremor e erros de rotação não são relevantes.)

	0	1
Desenha	☐	☐

feche os olhos



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QUESTIONÁRIO DE HISTÓRIA DE SAÚDE

Baseado em Rose (2003)

1. Já alguma vez lhe foi diagnosticada alguma das seguintes condições de saúde?	Sim	Não	**Se Sim, Ano do Diagnóstico:**
Ataque cardíaco			
Acidente Isquémico Transitório (AIT)			
Angina (Dor no peito)			
Hipertensão arterial			
Acidente Vascular Cerebral (AVC)			
Doença Vascular Periférica			
Neuropatias (alterações da sensibilidade)			
Doença Respiratória			
Doença de Parkinson			
Esclerose Múltipla			
Poliomielite ou Síndrome Pós-polio			
Epilepsia/Convulsões			
Outras doenças neurológicas			
Osteoporose			
Artrite Reumatóide			
Outros tipos de doenças artríticas (artrites)			
Artroses			
Problemas de visão ou de percepção da profundidade			
Problemas do ouvido interno/ infecções recorrentes do ouvido			
Problemas de Audição			
Problemas do cerebelo (ataxia, desequilíbrio e falta de coordenação no movimento)			
Outras alterações do movimento			
			(Cont. Folha seguinte)

Dependência de químicos (álcool e/ou drogas) ☐ ☐ ______

Depressão ☐ ☐ ______

Problemas de Coluna ☐ ☐ ______

2. Já alguma vez lhe foi diagnosticada alguma das seguintes condições de saúde?

Sim Não

Cancro ☐ ☐

Se Sim, descreva o tipo: ______

Sim Não

Artroplastia (Colocação de prótese articular) ☐ ☐

Se Sim, quantas vezes? ______

☐ Anca Direita

☐ Anca Esquerda

☐ Joelho Direito

☐ Joelho Esquerdo

Sim Não

Doenças Cognitivas ☐ ☐

Se sim, descreva a alteração: ______

Sim Não

Problemas de Visão não corrigidos ☐ ☐

Se sim, descreva a alteração: ______

Sim Não

Qualquer outro problema de Saúde? ☐ ☐

Se sim, descreva o problema:

3. **Neste momento, sofre de algum dos seguintes sintomas nos pés ou pernas?**

	Sim	Não
Entorpecimento	☐	☐
Formigueiro	☐	☐
Artrite	☐	☐
Edema/Inchaço	☐	☐

4. **Actualmente, tem alguma condição de saúde que o leva a consultar o médico com regularidade?**

Sim ☐ Não ☐

Se Sim, descreva as condições de saúde:

5. **Usa Óculos?**

Sim ☐ Não ☐

Se Sim, que tipo de óculos?

☐ Bifocais

☐ Lentes Progressivas

☐ Aumento apenas

☐ Tri-focais

6. Costuma ter uma consulta para avaliar sua visão (vista) pelo menos uma vez por ano?

Sim ☐ Não ☐

7. Usa Aparelho Auditivo?

Sim ☐ Não ☐

Se Sim, em que ouvido:

☐ Esquerdo

☐ Direito

☐ Nos Dois

8. Usa algum auxiliar de marcha (apoio para andar)?

Sim ☐ Não ☐

☐ Às vezes

Se Sim ou Às vezes, que tipo de auxiliar de marcha utiliza:

☐ Bengala

- [ ] Tripé (bengala com 3 pés)
- [ ] Quadripé (bengala com 4 pés)
- [ ] Andarilho
- [ ] Andarilho com rodas e banco

9. **Lista de Medicamentos que toma actualmente (incluindo os que toma à vezes e os produtos naturais ou de medicinas alternativas)**

Tipo de Medicação/Nome	Para que Condição de Saúde
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	
16.	
17.	
18.	
19.	
20.	
21.	
22.	

10. Durante o último ano, necessitou de cuidados médicos de urgência ou foi hospitalizado?

Sim ☐ Não ☐

Se Sim, diga quando é que isso aconteceu e explique brevemente porquê:

____

____

____

____

____

____

11. Já alguma vez teve algum problema de saúde ou sofreu alguma lesão/acidente que afectasse o seu equilíbrio ou a sua capacidade de andar sem ajuda?

Sim ☐ Não ☐

Se Sim, diga quando é que isso aconteceu e explique brevemente o problema de saúde ou lesão:

____

____

____

12a. Quantas vezes caiu nos últimos 6 meses?

Queda – "Evento inesperado no qual o participante vem parar ao chão, pavimento ou nível inferior" (ProFaNE; Lamb *et al.*, 2005)

Se caiu nos últimos 6 meses, por favor descreve detalhadamente o acidente:

a) Data: ______________________

b) Localização (ex: dentro de casa, na rua) ______________________

c) Razão da queda (ex: superfície irregular, descer escadas…) ______________________

d) Precisou de tratamento médico? ☐ Sim ☐ Não

e) Data: ______________________________

f) Localização
(ex: dentro de casa, na rua) ______________________________

g) Razão da queda
(ex: superfície irregular, descer escadas…) ______________________________

h) Precisou de tratamento médico?

☐ Sim

☐ Não

12b. Quantas vezes caiu no último ano?
Queda – "Evento inesperado no qual o participante vem parar ao chão, pavimento ou nível inferior" (ProFaNE; Lamb *et al.*, 2005)

Se caiu no último ano, por favor descreve detalhadamente o acidente:

a) Data: ______________________________

b) Localização
(ex: dentro de casa, na rua) ______________________________

c) Razão da queda
(ex: superfície irregular, descer escadas…) ______________________________

d) Precisou de tratamento médico?

☐ Sim

☐ Não

e) Data: ______________________________

f) Localização
(ex: dentro de casa, na rua) ______________________________

g) Razão da queda
(ex: superfície irregular, descer escadas…) ______________________________

h) Precisou de tratamento médico?

☐ Sim

☐ Não

i) Data: ____________________

j) Localização (ex: dentro de casa, na rua) ____________________

k) Razão da queda (ex: superfície irregular, descer escadas…) ____________________

l) Precisou de tratamento médico?

☐ Sim

☐ Não

13. Está preocupado em relação a quedas?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

14. Devido a esta preocupação, deixou de fazer coisa que costumava fazer ou gostava a de fazer?

Sim	Não
☐	☐

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QUESTIONÁRIO DE MEDO DE CAIR

FES - Versão Portuguesa
Melo (2011)

Versão Portuguesa da Falls Efficacy Scale (FES)

ABAIXO ESTÃO INDICADAS VÁRIAS TAREFAS.
Á FRENTE DELAS ENCONTRA-SE UMA LINHA QUE MEDE O GRAU DE CONFIANÇA, OU SEJA, O MEDO QUE TEM DE CAIR NA SUA EXECUÇÃO.
MARQUE NA LINHA COM UMA CRUZ O QUE SENTE AO EXECUTAR A TAREFA.

	Sem nenhuma Confiança				Minimamente Confiante					Muito Confiante
1. Vestir e despir-se	**1**	2	3	4	**5**	6	7	8	9	**10**
2. Preparar uma refeição ligeira	**1**	2	3	4	**5**	6	7	8	9	**10**
3. Tomar um banho ou duche	**1**	2	3	4	**5**	6	7	8	9	**10**
4. Sentar / Levantar da cadeira	1	2	3	4	**5**	6	7	8	9	**10**
5. Deitar / Levantar da cama	**1**	2	3	4	**5**	6	7	8	9	**10**
6. Atender a porta ou o telefone	**1**	2	3	4	**5**	6	7	8	9	**10**
7. Andar dentro de casa	**1**	2	3	4	**5**	6	7	8	9	**10**
8. Chegar aos armários	**1**	2	3	4	**5**	6	7	8	9	**10**
9. Trabalho doméstico ligeiro (limpar o pó, fazer a cama, lavar a louça)	**1**	2	3	4	**5**	6	7	8	9	**10**
10. Pequenas compras	**1**	2	3	4	**5**	6	7	8	9	**10**

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QUESTIONÁRIO DE ACTIVIDADE FÍSICA

BAECKE MODIFICADO
Voorrips et al (1991)

ACTIVIDADES DOMÉSTICAS

1. Costuma fazer trabalho doméstico leve (varrer, lavar loiça, reparar roupas, etc)?

nunca (< 1 vez por mês) ☐ 0
às vezes (apenas quando o parceiro ou outra ajuda não estão disponíveis) ☐ 1
muitas vezes (algumas vezes ajudado pelo parceiro ou outra ajuda) ☐ 2
sempre (só, ou com o parceiro) ☐ 3

2. Costuma fazer trabalho doméstico pesado (lavar o chão e janelas, transportar sacos do lixo, etc.)?

nunca (< 1 vez por mês) ☐ 0
às vezes (apenas quando o parceiro ou outra ajuda não estão disponíveis) ☐ 1
muitas vezes (algumas vezes ajudado pelo parceiro ou outra ajuda) ☐ 2
sempre (só, ou com o parceiro) ☐ 3

3. Para quantas pessoas cuida da casa (incluindo a sua pessoa; responda 0 se escolheu 'nunca' na questão 1 e 2).

☐

4. Quantos quartos mantém limpos, incluído a cozinha, quartos de dormir, garagem, casa de banho, sótão, etc.? (responda 0 se respondeu 'nunca' na questão 1 e 2).

nunca faço trabalho doméstico	1 a 6 quartos	7 a 9 quartos	≥ 10 quartos
☐ 0	☐ 1	☐ 2	☐ 3

5. Se em mais de um quarto, em quantos andares faz limpeza? (responda 0 se respondeu 'nunca' na questão 4).

☐

6. Costuma cozinhar ou ajudar na preparação das refeições?

nunca	algumas vezes (1 ou 2 vezes por semana)	muitas vezes (3-5 vezes por semana)	sempre (> 5 vezes por semana)
☐ 0	☐ 1	☐ 2	☐ 3

7. Quantos lanços de escadas costuma subir por dia? (1 lanço de escadas = 10 escadas).

nunca subo escadas	1 a 5	6-10	> 10
☐ 0	☐ 1	☐ 2	☐ 3

8. Se, se deslocar na sua cidade, que tipo de transporte usa?

nunca saio	carro	transporte público	bicicleta	a pé
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

9. Com que frequência costuma sair para fazer compras?

nunca	1 vez por semana	2 a 4 vezes por semana	todos os dias
☐	☐	☐	☐
0	1	2	3

10. Se sair para fazer compras, que tipo de transporte usa?

nunca saio	carro	transporte público	bicicleta	a pé
☐	☐	☐	☐	☐
0	1	2	3	4

ACTIVIDADES DESPORTIVAS

Pratica algum desporto? Sim ☐ Não ☐

- Qual é o desporto? ____________________ ☐☐.☐☐

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

Pratica um segundo desporto? Sim ☐ Não ☐

- Qual é o desporto? ____________________ ☐☐.☐☐

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

ACTIVIDADES DE TEMPOS LIVRES

Pratica outra actividade fisicamente activa? Sim ☐ Não ☐

- Qual é a actividade? ____________________ ☐☐.☐☐

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

Pratica uma 2ª actividade fisicamente activa? Sim ☐ Não ☐

- Qual é a actividade? ____________________

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

Pratica uma 3ª actividade fisicamente activa? Sim ☐ Não ☐

- Qual é a actividade? ____________________

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

Pratica uma 4ª actividade fisicamente activa? Sim ☐ Não ☐

- Qual é a actividade? ____________________

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

Pratica uma 5ª actividade fisicamente activa? Sim ☐ Não ☐

- Qual é a actividade? ____________________

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

Pratica uma 6ª actividade fisicamente activa? Sim ☐ Não ☐

- Qual é a actividade? ____________________

- Quantas horas por semana?

<1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	>8
☐	☐	☐	☐	☐	☐	☐	☐	☐
0.5	1.5	2.5	3.5	4.5	5.5	6.5	7.5	8.5

- Quantos meses por ano?

<1	1-3	4-6	7-9	>9
☐	☐	☐	☐	☐
0.04	0.17	0.42	0.67	0.92

Prehabilitation and rehabilitation nursing: Balance/fall risk in community-dwelling older adults - Randomized Controlled Trial

Prehabilitation e enfermagem de reabilitação: Equilíbrio/risco de quedas em adultos idosos residentes na comunidade - Ensaio Clínico Controlado Randomizado

IDNR | | | | | |

QUESTIONÁRIO DE QUALIDADE DE VIDA ASSOCIADA À SAÚDE

SF-36 - Versão Portuguesa
Ribeiro (2005)

Para responder coloque uma cruz no número que melhor descreve a sua saúde

1. Em geral, diria que a sua saúde é:				
Óptima	Muito Boa	Boa	Razoável	Fraca
1	2	3	4	5

2. Comparando com o que acontecia há um ano, como descreve o seu estado geral actual:				
Muito Melhor	Com algumas Melhorias	Aproximadamente igual	Um pouco pior	Muito Pior
1	2	3	4	5

3. As perguntas que se seguem são sobre actividades que executa no seu dia-a-dia. Será que a sua saúde o/a limita nestas actividades? Se sim, quanto:			
	Sim muito limitado/a	Sim um pouco limitado/a	Não nada limitado/a
a) Actividades violentas, tais como participar em desportos violentos ou mesmo correr ou levantar pesos.	1	2	3
b) Actividades moderadas, tais como deslocar uma mesa ou aspirar a casa	1	2	3
c) Levantar ou pegar nas compras de mercearia	1	2	3
d) Subir vários lanços de escadas (1 lanço=10 degraus)	1	2	3
e) Subir um lanço de escadas	1	2	3
f) Inclinar-se, ajoelhar-se ou baixar-se	1	2	3
g) Andar, mais de 1 kilómetro	1	2	3
h) Andar vários quarteirões ou grupos de casas	1	2	3
i) Andar um quarteirão ou grupo de casas	1	2	3
j) Tomar banho ou vestir-se sozinho/a	1	2	3

4. Durante as últimas 4 semanas teve, no seu trabalho ou actividades diárias, algum dos problemas apresentados a seguir como consequência do seu estado de saúde físico?		
	Sim	Não
a) Diminuiu o tempo gasto a trabalhar, ou noutras actividades	1	2
b) Fez menos do que queria	1	2
c) Sentiu-se limitado/a no tipo de trabalho ou noutras actividades	1	2
d) Teve dificuldade em executar o seu trabalho ou outras actividades (por exemplo foi preciso mais esforço)	1	2

		Sim	Não
5.	Durante as últimas 4 semanas teve, no seu trabalho ou actividades diárias, algum dos problemas apresentados a seguir devido a quaisquer problemas emocionais (tal como sentir-se deprimido/a ou ansioso/a)?		
a)	Diminuiu o tempo gasto a trabalhar, ou noutras actividades	1	2
b)	Fez menos do que queria	1	2
c)	Não executou o trabalho ou outras actividades tão cuidadosamente como era costume	1	2
d)	Teve dificuldade em executar o seu trabalho ou outras actividades (por exemplo foi preciso mais esforço)	1	2

6. Durante as últimas 4 semanas, em que medida é que a sua saúde física ou problemas emocionais interferiram no seu relacionamento social normal com a família, amigos, vizinhos ou outras pessoas?

Absolutamente nada	Pouco	Moderadamente	Bastante	Imenso
1	2	3	4	5

7. Durante as últimas 4 semanas, teve dores?

Nenhumas	Muito fracas	Ligeiras	Moderadas	Fortes	Muito fortes
1	2	3	4	5	6

8. Durante as últimas 4 semanas, em que medida é que a dor interferiu com o seu trabalho normal (tanto o trabalho fora de casa como o trabalho doméstico)?

Absolutamente nada	Pouco	Moderadamente	Bastante	Imenso
1	2	3	4	5

9. As perguntas que se seguem pretendem avaliar a forma como se sentiu e como lhe correram as coisas nas últimas 4 semanas.
Por cada pergunta coloque por favor uma cruz na resposta que melhor descreve a forma como se sentiu.

	Quanto tempo nas últimas 4 semanas:	Sempre	A maior parte do tempo	Bastante tempo	Algum tempo	Pouco tempo	Nunca
a)	Se sentiu cheio/a de vitalidade?	1	2	3	4	5	6
b)	Se sentiu muito nervoso/a?	1	2	3	4	5	6
c)	Se sentiu tão deprimido/a que nada o/a animava?	1	2	3	4	5	6
d)	Se sentiu calmo/a e tranquilo/a?	1	2	3	4	5	6
e)	Se sentiu com muita energia?	1	2	3	4	5	6
f)	Se sentiu triste e em baixo?	1	2	3	4	5	6
g)	Se sentiu estafado/a?	1	2	3	4	5	6
h)	Se sentiu feliz?	1	2	3	4	5	6
i)	Se sentiu cansado/a?	1	2	3	4	5	6

Appendix IV – Information to the participant document

(Portuguese Language)

Projecto ProBalance - Preabilitação e enfermagem de reabilitação: Equilíbrio/risco de quedas em adultos idosos residentes na comunidade - Ensaio Clínico Controlado Randomizado

Investigadora Responsável: Bruna Ornelas de Gouveia
Contacto telefónico: 92 4065152
E-mail: projecto.probalance@gmail.com

Folha de Informação ao Participante

Foi-lhe pedido para participar num estudo de investigação na área da Enfermagem de Reabilitação desenvolvido no âmbito de um Curso de Doutoramento em Ciências de Enfermagem.

A sua participação neste projecto significa que: a informação sobre a sua saúde em geral, equilíbrio e aptidão funcional será recolhida e analisada, juntamente com as informações de outras pessoas com idade superior a 65 anos, e fará parte de uma intervenção multidimensional para melhorar o seu equilíbrio e mobilidade, assim como, prevenir quedas.

Qual é o Objectivo deste Estudo?

Esta pesquisa tem como objectivos: (1) descrever as relações entre os riscos para a queda e a incidência destes eventos nos idosos e (2) estudar o efeito da intervenção de enfermagem de reabilitação na prevenção das quedas em idosos residentes na comunidade.

Porque as quedas (associadas a falta de equilíbrio e mobilidade) constituem causas muito importantes de dependência e morte nos idosos, este estudo pretende validar uma intervenção do enfermeiro de reabilitação que previna este problema. Assim, a informação recolhida irá ajudar a diminuir o risco de quedas nos participantes e, futuramente, de outros idosos.

O que é que este estudo envolve?

Este estudo desenvolve-se em 3 fases:

1ª Fase: Esta fase, já decorrida, diz respeito ao recrutamento. Foram aceites voluntários para participar no projecto, quer por resposta a publicitação ou após um contacto com o seu enfermeiro do Centro de Saúde ou outro profissional de referência da instituição que frequenta.

Todos os voluntários foram questionados sobre alguns aspectos da sua saúde e sujeitos uma avaliação do equilíbrio. Os voluntários com condições e indicação para participar no estudo, foram sorteados para integrar dois grupos: Grupo 1 e Grupo 2.

2ª Fase: Os participantes dos dois grupos serão questionados sobre vários aspectos da sua saúde que podem influenciar o seu risco de cair e serão sujeitos a uma avaliação de parâmetros clínicos (Ex: Pressão arterial, glicemia capilar, colesterol capilar), de parâmetros antropométricos (medidas do corpo), do equilíbrio e da aptidão funcional.

Os dois grupos serão avaliados inicialmente e em mais 1 momento, após 3 meses desde o início desta fase. O Grupo 1 iniciará o programa de reabilitação após a 1º avaliação e o Grupo 2 iniciará após a 2ª avaliação. A intervenção será constituída por 2 sessões educacionais pontuais e 2 sessões semanais de reabilitação, com a duração de 90 minutos, durante 3 meses.

Todas as avaliações individuais serão agendadas tendo em conta a sua disponibilidade e realizadas num ambiente privado, garantindo as condições máximas de privacidade. As sessões decorrerão em grupo, em ambiente de acesso controlado e participação restrita aos participantes do estudo.

3ª Fase: 3 meses após o fim da 2ª fase, será feita uma última avaliação de todos os parâmetros avaliados anteriormente. Será concluído o estudo, com encaminhamento de todos os participantes dos 2 grupos para os recursos de saúde necessários.

Durante a toda a duração do projecto, será solicitado ao participante que notifique a investigadora responsável de qualquer alteração significativa no seu estado de saúde, alteração da medicação habitual ou ocorrência de quedas.

A ocorrência de quedas deve ser registada em diário próprio, que será cedido pelo investigador.

Contactos regulares da equipa de investigação através do telefone poderão acontecer, caso o participante declare não conseguir efectuar o registo das quedas e para certificação do seu registo pelos restantes participantes.

Onde decorrerão as actividades deste estudos?

As sessões de reabilitação e de educação para a saúde serão realizadas numa sala de acesso restrito na Universidade da Madeira, Campus Universitário da Penteada (2º Andar, Sala 2.47).

As avaliações decorrerão no mesmo local.

A quem é pedido para participar?

Foi-lhe pedido para participar neste estudo porque tem idade superior a 65 anos, vive num domicílio familiar e pode apresentar risco de cair.

A pesquisa envolverá muitas pessoas com idade igual ou superior a 65 anos, voluntários residentes na Região Autónoma da Madeira.

Existem risco nesta participação?

O exercício prescrito será de baixa a moderada intensidade, equiparando-se ao nível de esforço necessário para o desempenho das suas actividades de vida diárias, pelo que não se prevê que a inclusão neste estudo acrescente risco para a sua saúde.

Os exercícios de reabilitação serão realizados com base na avaliação da saúde do participante, respeitando as orientações das instituições internacionais que regulamentam deste tipo de intervenções.

Durante todas as actividades será garantido o acompanhamento de um enfermeiro e controlo dos parâmetros de saúde que possam ser afectados pela intervenção.

Qualquer problema de saúde ou acidente que possa acontecer estará previsto num plano de emergência. Todos os custos decorrentes estarão cobertos no âmbito de um seguro de acidentes pessoais que será efectuado para cada participante que cobre despesas de tratamento, morte e invalidez.

Existem benefícios por participar?

Todos os participantes do estudo irão beneficiar de:

(1) um acompanhamento de saúde específico durante a duração do projecto, com duas ou três avaliações de saúde abrangentes;

(2) uma intervenção de enfermagem de reabilitação que pretende diminuir o risco de quedas nos participantes e melhorar a sua capacidade funcional ;

(3) um encaminhamento de um enfermeiro de reabilitação para recursos de saúde necessários.

Futuramente, a informação obtida neste estudo irá beneficiar outros idosos, permitindo intervenções mais eficazes para evitar as quedas e os problemas respiratórios agudos.

Quem terá acesso à minha informação?

Não será utilizado o seu nome em nenhum relatório, mas sim um número de identificação, atribuído a cada participante por ordem de inscrição.

Os dados de identificação dos participantes serão apenas do conhecimento da investigadora responsável e do participante, sendo esta informação destruída após conclusão do estudo e encaminhamento dos participantes para os recursos de saúde necessários.

A sua informação pessoal será sempre confidencial e só poderá ser revelada se solicitada pelas vias legais.

Está prevista a publicação dos resultados deste estudo no futuro, mas a sua identidade não será divulgada.

Quais serão as condições de privacidade?

Todas as avaliações individuais serão realizadas num ambiente particular, garantindo as condições de privacidade.

As sessões decorrerão em grupo, numa sala de acesso controlado e restrito aos idosos participantes do estudo.

Existem custos envolvidos?

Por participar neste estudo terá a seu cargo apenas as despesas relacionadas com o transporte para o local onde vão ocorrer: (1) as avaliações de saúde (3 momentos); (2) as sessões de reabilitação (2 vezes por semana durante 3 meses); e (3) as sessões de educação para a saúde (2 momentos apenas no mesmo período).

Todos os outros custos serão atribuídos ao investigador responsável.

Que tempo terei de dispender?

Ao participar neste estudo, ser-lhe-á pedido para dispender o tempo para:

- Os 3 momentos de avaliação (com fraccionamento e marcação de acordo com a sua disponibilidade),
- As sessões de educação para a saúde (2 vezes no período de 3 meses, com duração de 45 minutos) e

- As sessões de reabilitação (com a duração de 90 minutos, 2 vezes por semana durante 3 meses).

Os horários das sessões serão às segundas, terças, quartas, quintas e sexta-feiras, entre as 16h e as 17h30h, e sábados, entre as 10h e as 11h30. As avaliações serão em horário variável, durante os dias úteis à tarde e sábado durante todo o dia. Horários finais serão definidos após recrutamento, tendo em conta a disponibilidade e preferência dos participantes, mas os dois dias serão fixos para cada participante.

Quais são os meus direitos?

Antes de decidir participar neste estudo, será informado individualmente da natureza, dos fins, dos procedimentos e das metodologias, da identidade e contactos da investigadora responsável, das condições, benefícios, riscos e custos inerentes à sua participação. Ser-lhe-ão explicados todos os procedimentos, razões e efeitos decorrentes. Antes de tomar a sua decisão terá direito a esclarecer de dúvidas e pedir a opinião de terceiros. Receberá este documento assinado pela investigadora responsável.

Se recusar ou desistir da sua participação neste estudo, em qualquer momento, não irá sofrer qualquer dano ou prejuízo futuro, nem perder nenhum direito de saúde ou legal.

A quem posso contactar se tiver alguma questão ou preocupação?

Se tiver alguma dúvida sobre os seus direitos como participante, pode contactar a Enfermeira Bruna Ornelas de Gouveia (Investigadora responsável), através dos contactos acima descritos ou na sua morada institucional (Universidade da Madeira, Campus da Penteada, Centro de Competência Tecnologias da saúde).

A investigadora compromete-se a disponibilizar-se para responder a qualquer dúvida e a respeitar os princípios éticos que regulam o exercício da profissão de enfermagem, durante todo este processo de investigação.

A Investigadora Responsável

____

(Bruna Ornelas de Gouveia)

Data: ___________________

Appendix V – Informed consent

(Portuguese Language)

Projecto ProBalance - Preabilitação e enfermagem de reabilitação: Equilíbrio/risco de quedas em adultos idosos residentes na comunidade **-** Ensaio Clínico Controlado Randomizado

Investigadora Responsável: Bruna Ornelas de Gouveia

Contacto telefónico: 92 4065152

E-mail: projecto.probalance@gmail.com

Consentimento Informado

Eu, ____, fui informado(a) dos propósitos do estudo de investigação *Prehabilitation e enfermagem de reabilitação: Equilíbrio/risco de quedas em adultos idosos residentes na comunidade - Ensaio Clínico Controlado Randomizado* e tomei conhecimento das avaliações e intervenção a que me submeterei, assim como do seu objectivo.

Mais declaro que dou o meu consentimento para que dados anónimos a meu respeito possam ser guardados e processados por Bruna Ornelas de Gouveia, para fins de avaliação científica. Li (ou foi-me lida) a informação mencionada na Folha de Informação ao Participante. Entendo o significado desta informação e as minhas perguntas foram satisfatoriamente respondidas.

Assim, estando informado(a) e compreendendo os termos de participação, ofereço-me como voluntário(a) para participar neste estudo e consinto na recolha, uso e revelação da informação recolhida. Afirmo que tive tempo suficiente para decidir sobre a participação neste estudo e que ficará em minha posse um documento assinado pelo investigador responsável e datada.

Assinatura do Participante: _______________________________________**Data:** ___________

Assinatura da Investigadora: _____________________________________**Data:** ___________

Appendix VI – Ethics Committee approval document

(Portuguese Language)

REGIÃO AUTÓNOMA DA MADEIRA
SERVIÇO DE SAÚDE DA REGIÃO AUTÓNOMA DA MADEIRA, E.P.E.

Comissão de Ética para a Saúde do SESARAM,EPE

Parecer nº 06/2011

O Pedido:

Recebido do Conselho de Administração para parecer, pedido de autorização de Bruna Ornelas de Gouveia, Enfermeira, Professora Adjunta da UMA, para realização de um Estudo intitulado "Programas de Intervenção em Enfermagem de Reabilitação: Abordagem do Equilíbrio/Mobilidade e Função Respiratória em Adultos-Idosos residentes na Comunidade na Região Autónoma da Madeira - Um Estudo Quasi-Experimental", no âmbito do seu Doutoramento em Ciências de Enfermagem.

Parecer:

A CES/SESARAM,EPE, organizada e a funcionar de acordo com os requisitos das Normas da Boa Prática Clínica (ICHGCP *Guidelines*) e da legislação nacional em vigor (Dec. Lei nº 97/95, de 10 de Maio), composta por Dr. Edward Maul, Médico e Presidente, Dr. Ricardo Santos, Médico, Drª Joana Dias, Juíza, Dr. Emanuel Gomes, Psicólogo, Drª Raquel Tranquada, Médica, Dr. José Manuel Freitas, Teólogo e Enfermeira Isabel Santos, na sua reunião de 11 de Janeiro de 2011, decidiu dar parecer favorável ao pedido acima identificado por não levantar quaisquer problemas de ordem ética.

Funchal, 17 de Janeiro de 2011

O Presidente da CES

(*Edward Richard Maul*)

Avenida Luís de Camões – 9004-514 Funchal 291 705612 291 743783

Appendix VII – Publications

List of publications derived from this research

Date: June, 2014.

Gouveia, B.R., Jardim, H., & Martins, M.M. (2013). Cinesioterapia em Reabilitação Gerontológica: uma análise da literatura. *Referência, 3*(11), 133-142.

Gouveia, B.R., Jardim, H., Martins, M.M., Gouveia, E.R., Freitas, D.L., Maia, J.A., & Rose, D.J. (2014). Impact of the ProBalance program on balance in community-dwelling older adults from Madeira Island, Portugal. *Medicine & Science in Sports & Exercise, 46* (5) [S105], 105.

Gouveia, BR; Jardim, H; Martins, M; & Gouveia, ER. (2013). O perfil do adulto-idoso aderente a um programa de intervenção para melhorar o equilíbrio e prevenir quedas. *Referência, 3*(10) [Suppl], 130.

Gouveia, B.R., Jardim, H., & Rose, D.J. (2011). Prehabilitation and rehabilitation nursing: Balance/fall risk in community-dwelling older adults. Referência, 2(4) [Suppl], 432.

Gouveia, B.R., Jardim, H., & Martins, M.M. (2011). Foundation of gerontological rehabilitation nursing: applicability of the functional consequences theory. *Referência, 2*(4) [Suppl], 475.

Gouveia, B.R., Jardim, H; Martins, M., Gouveia, E.R., Freitas, D.L., Maia, J.A., & Rose, D.J. (2012). Balance and fall risk in community-dwelling older adults from Madeira, Portugal. *Journal of Aging and Physical Activity*, 20, [S1],S369.

Gouveia, B.R., Jardim, H., Martins, M., Fernandes, D., Silva, B., Vieira, L., Bettencourt, R., Quintal, C., Pinto, A., Rodrigues, R., & Gouveia, E.R. (2012). O perfil do idoso que cai: Um estudo de caracterização em idosos residentes na comunidade. Livro de Atas do Seminário Internacional de Desporto e Ciência, Universidade da Madeira, 2 a 3 de Março (in press).

The author of this thesis:

(Bruna Ornelas de Gouveia)